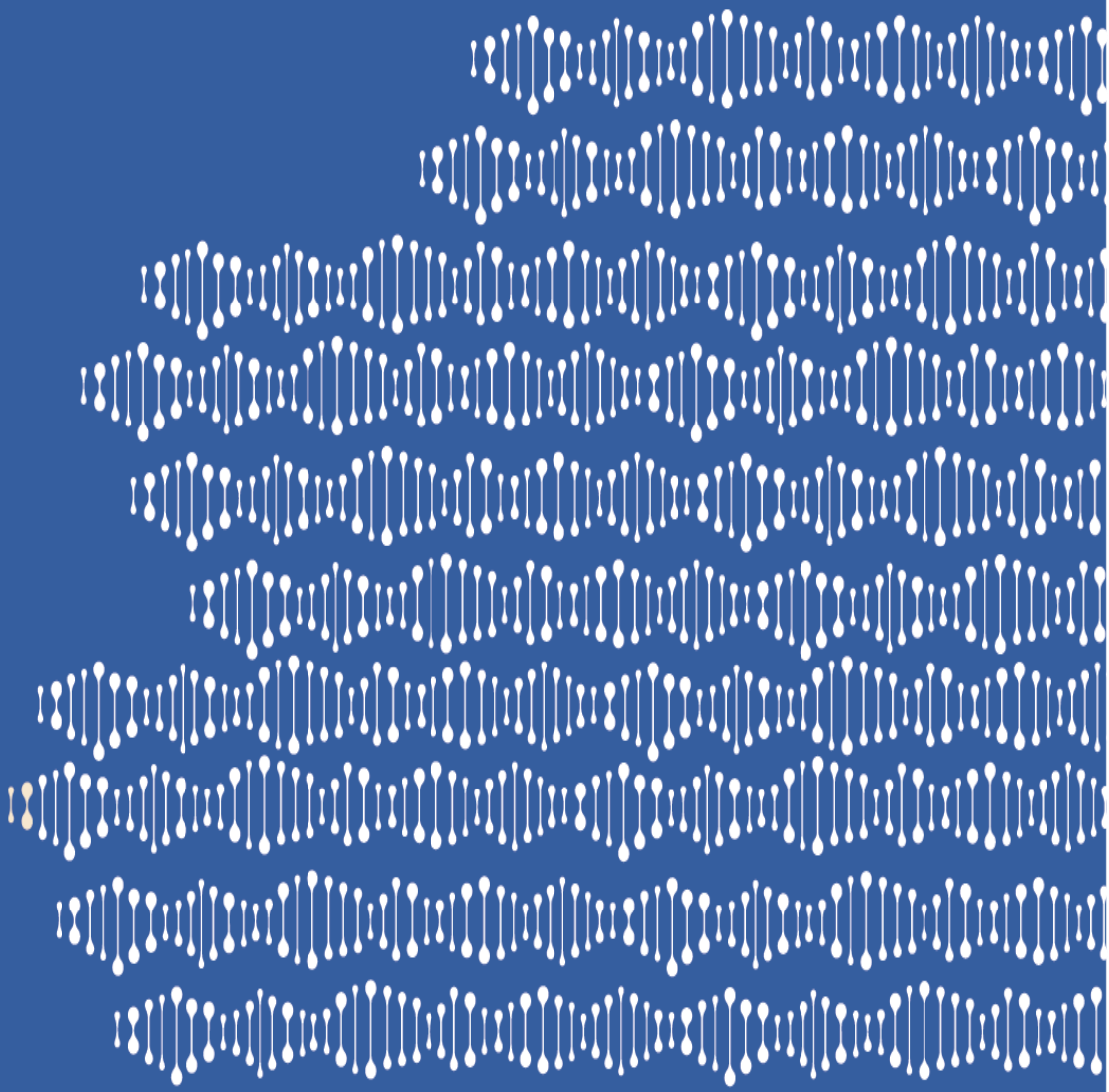
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

February 17, 2016



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Summary Overview of the February 17, 2016, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the February 17, 2016, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including the FY2016 proposed grant awards budget and programmatic funding targets, the annual report on the merit and progress of each of the CPRIT's three programs, and the Prevention Program funding issue.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Margaret Kripke will provide an update on the Academic Research Program and present the Program Integration Committee's recommendations for seven recruitment awards.

Information related to the Academic Research grant applications recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention and Communications Officer Report
Dr. Becky Garcia will give a report regarding the Prevention Program activities as well as an update on the agency's communications activities. Dr. Garcia's discussion will include an assessment of the recent 2015 CPRIT Conference and registrant survey results.

Chief Product Development Officer Report
Michael Lang will provide a Product Development Research Program update. One discussion item for Oversight Committee action is approval to execute the Ruga Corporation contract. The Oversight Committee approved the award at the November 2015 meeting, with certain contingencies to be addressed before the contract was executed. Mr. Lang will also provide an overview of the Product Development program and the Texas cancer research and development landscape.

Scientific Research and Prevention Programs Committee Appointments
The Chief Executive Officer has appointed one new member to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendation before the appointment is final. A biographical sketch for the appointee is included in the board packet.

Health and Safety Code 102.1062 Waiver
Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation" provides a process for the Oversight Committee to consider and approve a waiver of statutory conflicts of interest for individuals involved in the grant review or award process. The proposed

waiver applies to Dr. John Hellerstedt, the new Commissioner of the Texas Department of State Health Services.

Annual Reports Presented by the Advisory Committee on Childhood Cancer (ACCC) and University Advisory Committee
Pursuant to CPRIT's Administrative Rule § 701.13(7), each CPRIT advisory committee is required to submit a report to the Oversight Committee regarding the activities of the committee at least annually. The ACCC and UAC will present the annual reports and recommendations to the Oversight Committee at the meeting.

Chief Operating Officer Report
Heidi McConnell will report on CPRIT's debt issuance history and present the staff recommendation for the FY 2016 internal audit services contract.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, annual grantee certifications, desk reviews and site visits as well as grantee training and technical assistance.

Proposed Amendments to 25 T.A.C. Chapters 702 and 703 and Authorization to Publish in Texas Register
Ms. Doyle will present the three proposed amendments to CPRIT's administrative rules. The proposed amendments include the following:

- § 702.11: clarifies that a professional conflict of interest includes serving as a consultant or contractor for a grant applicant
- § 703.12: prohibits reimbursement of visa fees
- § 703.21: Adds an appeal process if the grantee's reimbursement of project costs is waived by operation of law

Final Order Approving Amendments to 25 T.A.C. Chapter 703
Ms. Doyle will summarize the comments received about the proposed rule changes initially presented to the Oversight Committee in November 2015. The rule amendments will become effective 20 days after filing the final order with the Secretary of State.

Public Information Act and Open Meeting Act Update Training
Texas Administrative Code § 702.21 requires Oversight Committee members to receive training on the Public Information Act (PIA) and the Texas Open Meetings Act (TOMA) after each regular session of the legislature. CPRIT's legal staff will discuss issues raised in the memos included in the meeting packet.

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Agenda

Texas State Capitol Extension
1400 N. Congress Avenue, Austin, Texas 78701
Room E1.012

February 17, 2016
9:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purposes permitted by the Act. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the November 19, 2015, meeting **TAB 1**
4. Public Comment
5. Chief Executive Officer Report **TAB 2**
   - FY 2016 Proposed Grant Awards Budget and Programmatic Funding Targets
   - CEO Report Pursuant to Health & Safety Code § 102.260(c)
   - CEO Report Pursuant to Health & Safety Code § 102.1063
6. Chief Scientific Officer Report and Grant Award Recommendations **TAB 3**
7. Chief Prevention and Communications Officer Report **TAB 4**
8. Chief Product Development Officer Report **TAB 5**
   - DP150127 Contract Execution
9. Scientific Research and Prevention Program Committee Appointments **TAB 6**
10. Health & Safety Code § 102.1062 Waiver **TAB 7**
11. Advisory Committee on Childhood Cancer – Annual Report **TAB 8**
12. University Advisory Committee – Annual Report **TAB 9**
13. Chief Operating Officer Report **TAB 10**
14. Internal Auditor Services Contract **TAB 11**
15. Chief Compliance Officer Report **TAB 12**
16. Proposed Amendments to 25 T.A.C. Chapters 702 and 703 and Authorization to Publish in *Texas Register* **TAB 13**
17. Final Order Approving Amendments to 25 T.A.C. Chapter 703 **TAB 14**
18. Public Information Act and Open Meeting Act Update Training **TAB 15**
19. Subcommittee Business
20. Personnel – Chief Executive Officer Annual Evaluation
21. Proposed Settlement – Peloton Therapeutics
22. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
23. Consultation with General Counsel
24. Future Meeting Dates and Agenda Items
25. Adjourn

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Minutes

November 19, 2015

1. Meeting Called to Order

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 10:30 a.m.

2. Roll Call /Excused Absences

Board Members Present:
Angelos Angelou (absent)
Donald (Dee) Margo
Pete Geren
Ned Holmes
Will Montgomery
Cynthia Mulrow, M.D.
Amy Mitchell
Bill Rice, M.D.
Craig Rosenfeld, M.D.

MOTION:

Presiding Officer Geren called for a motion to excuse the absence of Mr. Angelou.

Motion made by Dr. Rice and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

3. Adoption of Minutes from the November 19, 2015, Oversight Committee Meeting (TAB 1)

MOTION:

Presiding Officer Geren called for a motion to approve the minutes of the November 19, 2015 Oversight Committee meeting.

Motion made by Mr. Margo and seconded by Mr. Holmes

MOTION CARRIED UNANIMOUSLY

4. Public Comment

Presiding Officer Geren recognized Mr. Danny Ingram, Executive Vice President of the American Cancer Society (ACS) High Plains Division.

Mr. Ingram thanked the agency for its work and noted that ACS' mission aligns with CPRIT's mission. He presented an overview of ACS' Hope Lodge Initiative. Lack of transportation and/or lodging may contribute cancer patients not consistently receiving or completing recommended treatment. Hope Lodge fills that need. One Hope Lodge is located in Texas providing these free services to cancer patients, but ACS plans to open two more in Houston and Dallas.

Mr. Ingram responded to an Oversight Committee member question explaining that the program is need-blind versus need-based, and completely free to anyone. A donor campaign funds the costs. They begin operations with enough funding for at least three years of operations to ensure consistency of services. Donor funding campaigns will be continuous. He also explained that Hope Lodges are different from Ronald McDonald houses in that their services are for everyone, not just for families with sick children. They collaborate with Hospice and navigate patients to those services as needed.

There were no other requests for public comment.

5. Chief Executive Officer Report (TAB 2)

Mr. Wayne Roberts, Chief Executive Officer, reported on agency activities such as the recent *CPRIT Innovations in Cancer Prevention and Research Conference* held on November 9 and 10, 2015 and the status of selected CPRIT staff personnel recruitments.

Mr. Roberts also discussed grant-funding issues, including the process to ensure that Prevention Program grants do not exceed the 10% statutory maximum, FY 2016 funding available for grant awards, and targets for each program for planning purposes.

An Oversight Committee member asked whether Prevention funding had ever gone over the 10% statutory cap. Mr. Roberts said that the funding had exceeded the limit. Dr. Garcia reported that the Prevention Program is trying to address the issue by moving their grant cycle so that it is in the last funding cycle presented to the Oversight Committee in August. By that time, staff has a much clearer picture of the final budget. Ms. Doyle added the issue of possibly going over the statutory cap of 10% for Prevention arises when prospective recruits decline awards after the fiscal year closes. Staff has proposed amending CPRIT administrative rule 703.12 to provide transparency in our process for how we are establishing the budget for Prevention. It will call for the Chief Executive Officer to present the operating budget at the first meeting following the fiscal year and to update the budget at each meeting.

An Oversight Committee member stated that the agency would not want to find that they had awarded more than the amount the Legislature authorized. Mr. Roberts stated that staff should be able to avoid that situation by having updates at each meeting as appropriate.

An Oversight Committee member asked whether a set percentage of funding should be allotted to Academic Research and to Product Development Research because the large number of available Academic Research awards could outweigh the fewer available Product Development awards. Dr. Kripke pointed out that a drawback of setting specific amounts is

that one program may not have enough meritorious awards for all of the available funding, which leaves money unspent or approval of less worthy awards. If the money is unspent, it lowers the total amount of funds awarded used to calculate Prevention's 10% cap. CPRIT cannot carry forward the unspent funds in all cases into the next fiscal year.

Presiding Officer Geren requested that the Oversight Committee plan to consider this issue and develop a policy.

One Oversight Committee member asked if the agency could do anything to avoid the funding issues created when potential recruits decline grants after the fiscal year. Dr. Kripke said establishing a deadline to accept awards is an option. However, changing the timing of the awards is difficult because the awards follow the recruitment cycle of the universities. Moving the second Prevention Program cycle so that the awards come to the August Oversight Committee for approval helps alleviate the problem.

Presiding Officer Geren emphasized that CPRIT is going to do everything possible to abide by the 10% statutory cap on Prevention funding and legislative staff is aware of our commitment.

There were no further questions for Mr. Roberts.

6. Personnel – Chief Scientific Officer (Agenda Item 20 taken out of order)

Presiding Officer Geren announced that the Chief Executive Officer had requested an opportunity to update the Oversight Committee on the recruitment activities for the Chief Scientific Officer position. He stated that pursuant to Texas Government Code § 551.074, the meeting would go into closed session to discuss personnel issues related to the Chief Scientific Officer. He invited Wayne Roberts, Dr. Kripke, and Ms. Doyle to join the committee in the closed session.

Presiding Officer Geren announced the time the Oversight Committee went into closed session at 12:43 p.m.

Presiding Officer Geren reconvened the open meeting at 1:26 p.m. The Oversight Committee did not take action on this issue.

7. Chief Scientific Officer Report (TAB 3)

Presiding Officer Geren noted that the grant award recommendations were in the meeting materials handout titled "Proposed Grant Awards."

Dr. Margaret Kripke, Chief Scientific Officer recounted the Academic Research Program activities set out in her report in the Meeting Packet.

Dr. Kripke and the Oversight Committee discussed computational biology applications. She noted that the Scientific Review Council recommended only one computational biology application from cycle 16.1. Staff plans to meet with potential grant applicants and provide some guidance before the next round of applications. She anticipates that CPRIT will accept more applications in the future. An Oversight Committee member asked why the success rate was so low in computational biology. Dr. Kripke responded that the major reason appears that the biology part was weak even though a collaborator in biology was required. Many times the named collaborator had little input into the actual process. Reviewers also felt that applications were lacking in not having a demonstration project. The University Advisory Committee has provided feedback that many computational biologists are not primary investigators on grants and therefore not versed in grant application process. More training for computational biology applicants could help alleviate these issues.

In response to an Oversight Committee member's question, Dr. Kripke said they would explore the feasibility of adding a computational biology component to the individual investigator requests for application.

After Dr. Kripke presented the data on cancer by site, an Oversight Committee member noted the percent of grants targeting pancreatic cancer seems low in comparison to other targeted cancers.

Dr. Kripke noted that this cycle there were 13 applications for training grants and six of those were renewals. Of those six, the PIC recommended only three for funding. There were seven new applications for training grants. CPRIT allowed institutions to submit more than one application if one of the applications was in the area of prevention or epidemiology, one of the seven submitted was in this area.

In the area of recruitment awards, the PIC was recommending an extraordinarily large dollar amount for approval. The institutions are beginning to recruit senior researchers and those awards are more expensive. This is something that will need to be monitored going forward because they will compete with the academic research and product development grants for available funds. With that in mind, Mr. Roberts asked if the Oversight Committee wanted to prioritize the younger, up and coming researchers over the more senior established researchers. An Oversight Committee member noted that recruitment of established researchers includes funding to support their research and they contribute to economic development. Dr. Kripke said there are reasons to fund both new and established investigators and it will be a policy decision for the Oversight Committee.

An Oversight Committee member requested that Dr. Kripke routinely provide information on how many people investigators bring with their grants. Dr. Kripke stated this would also be an appropriate time to start surveying grantees on what they have accomplished and how successful they have been in terms of generating new funding or creating new jobs.

Presiding Officer Geren requested that Mr. Roberts provide information to the Oversight Committee on how to survey former grantees to determine their continuing contributions to cancer research.

Dr. Kripke presented the following Academic Research award recommendations for the Oversight Committee's consideration:

Academic Research Grant Award Recommendations

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160157	The University of Texas Southwestern Medical Center	Cancer Intervention and Prevention Discoveries Program	RTA-Renewal	$3,993,250
RP160192	Baylor College of Medicine	Decoding Cellular Heterogeneity of Malignant Glioma	IIRA	$899,701
RP160451	Baylor College of Medicine	Protein Truncation Mutations in WIP1: Effects on Cancer and Hematopoiesis	IIRA	$900,000
RP160180	The University of Texas Southwestern Medical Center	Development of Therapeutics Targeting Truncated Adenomatous Polyposis Coli (APC) as a Novel Prevention and Intervention Strategy for Colorectal Cancer	IIRA	$900,000
RP160237 *	The University of Texas M. D. Anderson Cancer Center	A novel epigenetic reader as therapeutic target in MLL-translocated pediatric leukemias	IIRACC A	$900,000
RP160283	Baylor College of Medicine	Baylor College of Medicine Comprehensive Cancer Training Program	RTA-Renewal	$3,986,268
RP160487	The University of Texas Health Science Center at San Antonio	Cytokine signaling in Ewing sarcoma	IIRACC A	$1,200,000
RP160030	The University of Texas Southwestern Medical Center	A Randomized Controlled Trial (RCT) of Patient Navigation for Lung Cancer Screening in an Urban Safety-Net System	IIRAP	$1,492,616
RP160384	Baylor College of Medicine	Promoting The Functions of Memory T cells for Adoptive T cell Therapy	IIRA	$887,676

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160318	The University of Texas Southwestern Medical Center	Role of Long Non-Coding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	IIRA	$886,652
RP160589	Texas AgriLife Research	Arylhydrocarbon receptor mediated modulation of colorectal cancer by microbiota metabolites	IIRAP	$890,840
RP160190 **	The University of Texas Southwestern Medical Center	Pediatric Radiation Oncology with Movie Induced Sedation Effect (PROMISE)	IIRACC A	$900,000
RP160497	The University of Texas M. D. Anderson Cancer Center	Amplified gold nanoparticle-mediated radiosensitization of tumors	IIRA	$899,309
RP160229	The University of Texas M. D. Anderson Cancer Center	Imaging-based quantitative analysis of vascular perfusion and tissue oxygenation to improve therapy of hepatocellular carcinoma	IIRA	$885,901
RP160169	The University of Texas Southwestern Medical Center	Molecular Mechanism of NLRP12-mediated Regulation of Colorectal Cancer	IIRA	$897,707
RP160249 ***	The University of Texas Southwestern Medical Center	DIS3L2 in Childhood Wilms Tumor: Mechanism to Medicines	IIRACC A	$1,200,000
RP160089	The University of Texas Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A new metabolic liability in non-small cell lung cancers	IIRA	$900,000
RP160501	The Methodist Hospital Research Institute	De-Orphanizing TLX: Implications for Glioblastomas	IIRA	$878,969
RP160622	The University of Texas Southwestern Medical Center	Computational live cell histology	IIRACB	$392,779

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160097	Baylor College of Medicine	Cancer Prevention Post-Graduate Training Program in Integrative Epidemiology	RTA	$2,986,890
RP160015	The University of Texas Health Science Center at Houston	Collaborative Training of a New Cadre of Innovative Cancer Prevention Researchers	RTA-Renewal	$4,000,000
RP160340	The University of Texas Southwestern Medical Center	The role of the Lats kinases in sarcomatoid renal cell carcinoma	IIRA	$899,598
RP160183	The University of Texas M. D. Anderson Cancer Center	Exploiting molecular and metabolic dependencies to optimize personalized therapeutic approaches for melanomas	IIRA	$900,000
RP160232	The University of Texas M. D. Anderson Cancer Center	Understanding Biological and Physical Factors Affecting Response to Proton Therapy to Improve its Clinical Effectiveness	IIRA	$879,362
RP160022	Baylor College of Medicine	Role of Cohesin in Hematopoiesis and Myeloid Leukemia in Children with Down Syndrome	IIRACC A	$1,905,638
RP160242	The University of Texas M. D. Anderson Cancer Center	Mechanisms and targeting strategies for SWI/SNF mutations in cancer	IIRA	$900,000
RP160440	The University of Texas Southwestern Medical Center	Targeting the undruggable: a first- in- class inhibitor of the HIF-2 transcription factor	IIRA	$899,412
RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	IIRAP	$1,497,595
RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	IIRA	$900,000

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	IIRA	$841,606
RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody- based tumor detection using PET	IIRA	$887,134
RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network	IIRA	$900,000
RP160211	The University of Texas Southwestern Medical Center	Novel tumorigenic mechanisms of the LKB1 tumor suppressor in endometrial and cervical cancer	IIRA	$896,653
RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	IIRA	$884,315
RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	IIRAP	$899,617
RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	IIRA	$828,060
RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	IIRA	$900,000
RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	IIRA	$900,000

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	IIRA	$891,938
RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	IIRA	$900,000
RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression	IIRA	$888,429
RP160121	The University of Texas M. D. Anderson Cancer Center	Clinical Safety and Efficacy of Third party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	IIRA	$900,000
RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	IIRAP	$897,570
RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non-coding RNAs: mechanism and their role in cancer development	IIRA	$900,000
RP160512	The University of Texas Health Science Center at San Antonio	Integrin-mediated IL-18 signaling in the prevention and treatment of inflammation-associated colorectal cancer	IIRA	$859,620
RP160577	Baylor Research Institute	A novel function of Itch in controlling IL-17-induced inflammation in colon cancer	IIRA	$900,000

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160617	The University of Texas at Dallas	Optimizing therapeutic strategies against lung cancer using Multi- Modality Imaging	IIRA	$899,999
RP160493	The University of Texas Southwestern Medical Center	Characterization and pharmacological targeting of the oncogenic activity of Jumonji enzymes	IIRA	$899,997
RP160054	Baylor College of Medicine	The CTC Circulator Phenotype: Insights into Mechanisms of Breast Cancer Dormancy	IIRA	$884,332
RP160235	The University of Texas Health Science Center at Houston	Regulation of tumor aggressiveness and immune suppression in lung adenocarcinoma	IIRA	$900,000
RP160150	The University of Texas M. D. Anderson Cancer Center	Radiogenomic Screen to Identify Novel Proliferation-associated Glioblastoma Genomic Therapeutic Targets: Discovery and Mechanistic Validation Study	IIRA	$897,627
RP160460	Rice University	High resolution imaging for early and better detection of bladder cancer	IIRAP	$873,765
RP160471	The University of Texas M. D. Anderson Cancer Center	Identifying new epigenetic vulnerabilities in pancreatic	IIRA	$900,000
RP160462	Baylor College of Medicine	Systematic identification of small molecule inhibitors that manipulate telomerase activities	IIRA	$898,288

App ID	Organization/ Company	Application Title	Mech.	Award Amount
RP160035	Baylor College of Medicine	The role of Prdm16 and histone H3 lysine 9 methyltransferase complex in MDS	IIRA	$872,157

* RP160237 - The peer review panel recommended reducing the budget to $300,000 per year for 3 years for a total of $900,000 based on the scope and depth of the work proposed.

** RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to $300,000 per year for 3 years for a total of $900,000. The final score was based on revised scope with full deletion of Aim 4.

*** RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to $300,000 per year for 4 years for a total of $1,200,000.

IIRA = Individual Investigator Research Awards
IIRACB = Individual Investigator Research Awards for Computational Biology
IIRACCA = Individual Investigator Research Awards for Cancer in Children and Adolescents
IIRAP = Individual Investigator Research Awards for Prevention and Early Detection
RTA = Research Training Awards
RTA-R = Research Training Awards - Renewal

Academic Research Recruitment Grant Award Recommendations

App ID	Candidate	Organization/Company	Mech.	Budget Requested
RR160019	Dung-fang Lee	The University of Texas Health Science Center at Houston	RFT	$2,000,000
RR160020	Wei Yang	The University of Texas at Austin	REI	$6,000,000
RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	$4,000,000
RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	$2,000,000
RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	$2,000,000

RFT = Recruitment of First-Time, Tenure-Track Faculty Members
REI = Recruitment of Established Investigators
RRS = Recruitment of Rising Stars

COMPLIANCE CERTIFICATION

Mr. Vince Burgess, Chief Compliance Officer, presented his report on the review process for the grant awards recommended to the Oversight Committee. He certified that recommended awards complied with applicable statutory and administrative requirements for the eight academic research slates, the five prevention slates, and the one product development research slate presented for approval at this meeting.

CONFLICT OF INTEREST NOTIFICATIONS

Presiding Officer Geren stated for the record that no Oversight Committee member reported a conflict of interest with any application considered today. No other conflicts were reported.

Presiding Officer Geren stated that rather than taking separate votes on individual grant mechanisms, the Oversight Committee would first take a vote on the individual investigators awards and training grant awards, and then a vote on recruitment grant awards. He noted for the record that a vote to approve the awards would also be an approval of the changes recommended by the peer review committees for RP160249, RP160237, and RP160190.

MOTION:

Presiding Officer Geren entertained a motion to approve each of the Program Integration Committee's recommendations for Individual Investigator awards and Training Grant awards.

Motion made by Mr. Montgomery and seconded by Mr. Margo.

MOTION CARRIED UNANIMOUSL**Y**

MOTION:

Presiding Officer Geren entertained a motion to approve each of the Program Integration Committee's recommendations for Recruitment Grant awards.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

MOTION:

Presiding Officer Geren entertained a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff, and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion made by Mr. Montgomery and seconded by Mr. Margo.

MOTION CARRIED UNANIMOUSLY

8. Chief Prevention and Communications Officer Report (TAB 4)

Presiding Officer Geren recognized Dr. Rebecca Garcia to report on the Prevention program activities from August 2015 through November 2015. Dr. Garcia recounted the information provided in the Agenda Packet. She also reported that she was the keynote speaker at a health fair event, "Dia de la Mujer," held on October 3, 2015, sponsored by Telemundo Amarillo. The event attracted over 500 women.

Grant Award Recommendations:

Dr. Garcia presented the Program Integration Committee's recommendation to approve grants for twelve projects totaling $13,247,742. The grant recommendations are presented in five slates corresponding to the grant mechanisms:

Evidence-Based Cancer Prevention Services

App ID	Project Title	Project Director	Organization	Award Amount
PP160042	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	$1,295,493
PP160010	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,409,909
PP160027	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	$1,374,127

Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition

App ID	Project Title	Project Director	Organization	Award Amount
PP160023	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	$2,299,753

Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services

App ID	Project Title	Project Director	Organization	Award Amount
PP160049	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	$1,500,000

App ID	Project Title	Project Director	Organization	Award Amount
PP160011	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson, Gail	The University of Texas Health Science Center at San Antonio	$1,500,000
PP160047	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and cervical cancer among Latinas	Savas, Lara	The University of Texas Health Science Center at Houston	$1,387,005
PP160036	Establishing a Comprehensive Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Association	$1,101,986

Cancer Prevention Promotion and Navigation to Clinical Services

App ID	Project Title	Project Director	Organization	Award Amount
PP160032	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei-Shih	Texas A&M University	$399,993
PP160056	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundation	$379,698

Dissemination of CPRIT-Funded Cancer Control Interventions

App ID	Project Title	Project Director	Organization	Award Amount
PP160048	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	$300,000
PP160051	Dissemination of an Evidence-Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez, Maria E	The University of Texas Health Science Center at Houston	$299,778

COMPLIANCE CERTIFICATION

Presiding Officer Geren noted for the record that Mr. Burgess already certified the review process for all the grant awards recommended to the Oversight Committee during this meeting during the discussion on Agenda Item 7.

CONFLICT OF INTEREST NOTIFICATIONS

Presiding Officer Geren stated for the record that no Oversight Committee member reported a conflict of interest with any application considered today. No other conflicts were reported.

MOTION:

Presiding Officer Geren entertained a motion to approve each of the Program Integration Committee's recommendations for Prevention Grant awards.

Motion was made by Mr. Montgomery and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

MOTION:

Presiding Officer Geren entertained a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff, and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion was made by Mr. Montgomery and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

Contract Extension for PP120029 (TAB 4)

Presiding Officer Geren recognized Ms. Doyle to present the recommendation to approve a contract extension for up to six months for grant award PP120029. The contract extension will allow the Texas Department of State Health Services (DSHS) to use remaining grant funds to pay for an independent audit required by CPRIT's award contract. The approval of the Oversight Committee is necessary because DSHS failed to request a contract extension within the time specified by CPRIT's administrative rules that would have allowed the Chief Executive Officer to approve the extension.

MOTION:

Presiding Officer Geren entertained a motion to approve a contract extension for PP120029 through February 28, 2016.

Motion was made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

9. Chief Product Development Officer Report (TAB 5)

Presiding Officer Geren recognized Mr. Michael Lang, Chief Product Development Officer to report on the activities of the Product Development program. He recounted the information in the Agenda Packet.

Grant Award Recommendations

Presiding Officer Geren called upon Mr. Lang to present the Program Integration Committee's recommendation.

Mr. Lang laid out the proposed Product Development award totaling $20 million to Ruga Corporation (Ruga) for discussion. Ruga is developing a drug for a specific type of leukemia that is in the pre-clinical phase of development. The award allows the company to complete the pre-clinical phase and move the drug forward in the FDA/IND approval process and into a Phase 1 clinical study. The renowned primary investigator's relocation to Texas will help build the cancer research ecosystem.

Mr. Lang reported that the Product Development Review Council (PDRC) was concerned that the license agreement with Stanford University has an unusually high royalty rate. Approval of the award should include a contingency requiring Ruga to renegotiate the license agreement to a standard royalty rate. Another recommended contingency is that Ruga hires an externally facing chief executive officer. The company is new and the primary investigator has been acting as the chief executive officer. The Product Development Review Council (PDRC) also noted a potential issue for clarification related to royalty stacking that might result from their manufacturing contract with FujiFilm Diosynth. The company will also have to report to CPRIT regarding the pre-IND meeting with the FDA.

Mr. Lang reports that the company will be located in Houston. In response to a question from an Oversight Committee member, Mr. Lang stated that the royalty with Stanford is unusually high for this stage in development (15%).

Ms. Doyle pointed out that the company must resolve the contingencies prior to award contract execution. A timeline has been set of May 1, 2016. If for some reason Ruga is unable to renegotiate the royalty rate, the grant money will again become available to fund other grants in this fiscal year.

An Oversight Committee member inquired why a company located in California, where there are other funding opportunities, is coming to Texas. Mr. Lang believes that CPRIT funding and the ecosystem being built in Texas are primary factors in their decision to relocate.

An Oversight Committee member inquired how CPRIT's approval of the renegotiated rate and other contingencies would occur. Ms. Roberts and Ms. Doyle stated that the PDRC recommended that the PDRC review any agreements and make recommendations to CPRIT's Chief Executive Officer.

Product Development Research Grant Award Recommendation

App ID	Company Name	Project	Requested Budget
DP150127	Ruga Corporation	Engineered AXL Decoy Receptor for Treatment of AML & Solid Tumors	$20,000,000

COMPLIANCE CERTIFICATION

Presiding Officer Geren noted for the record that Mr. Burgess already certified the review process for all the grant awards recommended to the Oversight Committee during this meeting during Item 7.

CONFLICT OF INTEREST NOTIFICATIONS

Presiding Officer Geren stated for the record that no Oversight Committee member reported a conflict of interest with any application considered today. No other conflicts were reported.

MOTION:

Presiding Officer Geren entertained a motion to approve the Program Integration Committee's recommendation for a Product Development Research Grant award to Ruga Corporation, subject to the stated contingencies and the change proposed by Dr. Rosenfeld that Ruga be required to provide the pre-IND meeting minutes to CPRIT for consideration and possible action prior to beginning the second tranche of funding.

Motion was made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

MOTION:

Presiding Officer Geren entertained a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff, and to authorize the Chief Executive Officer to sign the contract on behalf of CPRIT, with the understanding that the Chief Executive Officer and the Chief Product Development Officer will report to the Product Development Subcommittee for input prior to the contract execution and that the Product Development Subcommittee will make a recommendation to the Chief Executive Officer. Further, if a circumstance arises where the Product Development Subcommittee and the Chief Executive Officer do not agree, the Chief Executive Officer will bring the matter back to the Oversight Committee before proceeding.

Motion was made by Mr. Holmes and seconded by Dr. Rice.

MOTION CARRIED UNANIMOUSLY

MOTION:

Pursuant to the General Appropriations Act, Article IX, Section 4.03(a), Presiding Officer Geren called for a motion to authorize CPRIT to disburse grant funds via advance payments to Ruga Corporation upon execution of the award contract and the successful completion of tranches.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

10. Scientific Research and Prevention Program Committee Appointments (TAB 6)

Presiding Officer Geren call on Mr. Roberts to present the nominations for the Scientific Research and Prevention Program Committees.

Presiding Officer Geren noted that the Nominations Subcommittee had recommended approval of the proposed nominations.

MOTION:

Presiding Officer Geren called for a motion to approve the Scientific Research and Prevention Program Committee appointments.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

11. Internal Auditor Report (TAB 7)

Ms. Alyssa Martin of Weaver and Tidwell, CPRIT's internal auditor contractor, presented the following reports:

- Internal Audit Report over Grant Management
  Dr. Rice noted that the Audit Subcommittee had requested regular updates on progress of audit findings in order to ensure CPRIT addresses issues timely.
- Internal Audit Follow Up Procedures Report over Prior Year Governance and Information Technology Findings
  In response to an Oversight Committee member question, Ms. Martin stated they did not re-perform a full internal audit over Governance or Information Technology. They only performed review of areas with prior findings.
- Internal Audit Follow Up Procedures Report over Prior Year Grantee Monitoring Audit findings
- Internal Audit Report over Expenditures

Presiding Officer Geren reported that the Audit Subcommittee recommended that the Oversight Committee approve these four audit reports.

MOTION:

Presiding Officer Geren called for a motion to approve the Internal Audit Report over Grant Management.

Motion was made by Dr. Rice and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

MOTION:

Presiding Officer Geren called for a motion to approve the Internal Audit Follow Up Procedures Report over Prior Year Governance and Information Technology Findings.

Motion was made by Mr. Montgomery and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

MOTION:

Presiding Officer Geren called for a motion to approve the Internal Audit Report over Prior Year Grantee Monitoring Audit Findings.

Motion was made by Mr. Montgomery and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

MOTION:

Presiding Officer Geren called for a motion to approve the Internal Audit Report over Expenditures.

Motion was made by Mr. Montgomery and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

FY 2016-FY 2018 Internal Audit Plans

Ms. Martin presented the proposed three-year internal audit plan for FY 2016 through FY 2018. Developing a plan that covers three years allows the agency to plan audits that consistently cover medium to high-risk functions, as defined by the agency's risk assessment. It allows agency staff to implement procedures to address any audit recommendations and the internal auditor to test the effectiveness those new procedures against the original findings.

Ms. Martin explained that with the approval of the plans for three years, the FY 2016 internal audit plan is incorporated into the FY 2015 Internal Audit Annual Report that the Oversight Committee will take action on next.

Presiding Officer Geren pointed out that information security is such a high risk for any organization that it should be reviewed regularly and suggested that an information security audit be included in CPRIT's audit plan every year, not only in FY 2016.

Ms. Martin responded that CPRIT could incorporate the suggestion in the annual risk assessment process that internal audit and agency staff will perform toward the end of FY 2016. It will adjust the audit plans for FY 2017 and future years.

Presiding Officer Geren stated that the Audit Subcommittee recommended that the Oversight Committee approve the FY 2016-FY 2018 Internal Audit Plans.

MOTION:

Presiding Officer Geren called for a motion to approve the FY 2016-FY 2018 Internal Audit Plans

Motion was made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

FY 2015 Internal Audit Annual Report

Ms. Martin presented the FY 2015 Internal Audit Annual Report, explaining that it incorporates all of the required elements required by the State Auditor's Office. Once approved by the Oversight Committee, CPRIT will submit the report to the State Auditor's Office and post it on CPRIT's website.

Presiding Officer Geren stated that the Audit Subcommittee recommended that the Oversight Committee approve the FY 2015 Internal Audit Annual Report.

MOTION:

Presiding Officer Geren called for a motion to approve the FY 2015 Internal Audit Annual Report.

Motion was made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

12. FY 2016 Program Priorities (TAB 8)

Mr. Roberts presented the FY 2016 Program Priorities for the committee's consideration and approval.

MOTION:

Presiding Officer Geren called for a motion to approve the FY 2016 Program Priorities.

Motion was made by Dr. Rosenfeld and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

13. Proposed Amendment to Oversight Committee Bylaws (TAB 9)

Ms. Doyle explained that the proposed changes to the CPRIT Oversight Committee Bylaws Section 6.3 clarify that the Chief Executive Officer has contract execution authority, subject to approval by the Oversight Committee and specific delegation when necessary. The changes also authorize the Chief Operating Officer to execute contracts, including grant award contracts, in the absence of the Chief Executive Officer with prior notification to the Oversight Committee.

Presiding Officer Geren noted that the Board Governance Subcommittee had reviewed the changes and recommended approval.

MOTION:

Presiding Officer Geren entertained a motion to approve the proposed amendment to Section 6.3 of the Oversight Committee bylaws.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

14. Subcommittee Assignments (TAB 10)

Presiding Officer Geren reports that based on the Oversight Committee discussion regarding realignment of the subcommittee membership, he and the committee vice chair have recommended subcommittee assignments as presented in the meeting materials for this meeting for the committee's consideration.

MOTION:

Presiding Officer Geren entertained a motion to approve the subcommittee assignments as proposed for FY 2016-FY 2017.

Motion was made by Mr. Holmes and seconded by Dr. Rice.

MOTION CARRIED UNANIMOUSLY

15. Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish in *Texas Register* (TAB 11)

Ms. Kristen Doyle, General Counsel, presented the many proposed rule amendments to Texas Administrative Code. One of the proposed changes provides more clarity for the process of determining the 10% of grant funds available for prevention grants. A proposed rule also outlines a process for the Chief Executive Officer to approve a no cost extension request that the grantee submits after the required timeframe. In response to a question from the Oversight Committee, Ms. Doyle stated that the proposed rules provide an example of the agency formalizing its commitment to transparency.

MOTION:

Presiding Officer Geren entertained a motion to approve the proposed rule changes for publication in the *Texas Register* for public comment.

Motion was made by Ms. Mitchell and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

16. Final Order Approving Amendments to 25 T.A.C. Chapter 703 (TAB 12)

Ms. Doyle presented the final order approving amendments to CPRIT's administrative rules. The Oversight Committee preliminarily approved the changes in September 2015. One of the rule changes allows the Prevention grantees to use grant funds for up to 5% of indirect costs. The other change implements a new requirement of compliance training for all grantees. CPRIT published the proposed rules in the *Texas Register* for public comment.

MOTION:

Presiding Officer Geren entertained a motion to approve the final order adopting CPRIT's rule changes and to direct staff to file the order with the Secretary of State.

Motion was made by Dr. Rice and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

17. Advisory Committee on Childhood Cancer – Charter Amendment (TAB 13)

Dr. Kripke presented the proposed amendments to the charter of the Advisory Committee on Childhood Cancer. The primary change is to the membership makeup—the committee wants to have more than one person from the larger institutions across the state.

MOTION:

Presiding Officer Geren entertained a motion to approve the changes as proposed to the Advisory Committee on Childhood Cancer charter.

Motion was made by Dr. Rice and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

18. Chief Operating Officer Report (TAB 14)

Ms. Heidi McConnell, Chief Operating Officer, presented information on the following topics.

<u>CPRIT Financial Overview for FY 2015, Quarter 4</u>

- FY 2015, Quarter 4 Operating Budget
- FY 2015, Quarter 4 Performance Measures
- Debt Issuance History

Activities since September 1, 2015

- Annual Financial Report
- Annual Financial Audit
- FY 2016 Operating Budget

There were no questions for Ms. McConnell.

19. Chief Compliance Officer Report (TAB 15)

Mr. Vince Burgess, Chief Compliance Officer, reported on the activities of the Compliance program.

- Submission Status of Required Grant Recipient Reports
  Mr. Roberts noted that last year there were a large number of out-of-compliance reports and the agency needed to thoroughly investigate issues behind the non-compliance. He stated that under the leadership of Ms. McConnell and Mr. Burgess, staff have upheld their commitment to identify the causes and to reduce the number of non-compliant grants.
- FSR Reviews
- Desk Reviews
- On-site Reviews
- Single Audit Tracking
- Training and Technical Assistance

Presiding Officer Geren said that now that CPRIT has experience with collecting the reports and reviewing the captured information, he would ask that staff consider whether the reports actually capture needed information and if collecting that information is overly burdensome to grantees.

There were no questions for Mr. Burgess.

20. Chief Prevention and Communications Officer Report (TAB 16)

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, presented an overview of the agency's communications activities from August 2015 through Nov. 19, 2015. She also commended Jeff Hillary, Communications Specialist; Ramona Magid, Senior Program Manager for Prevention; and Therry Simien, Information Technology Officer, for their work to make the 2015 CPRIT conference a success. More than 820 people attended the conference and 238 provided written evaluations. The feedback was overwhelmingly positive. Dr. Garcia will draft a conference report for the Oversight Committee.

Dr. Garcia also reports that the "Achievements Report" has been redesigned and updated, CPRIT's message platform is being updated, and that staff are beginning to prepare materials and messaging for the legislative session.

21. Subcommittee Business

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item.

22. Compliance Investigation Pursuant to Health & Safety Code § 102.2631

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item.

23. Consultation with General Counsel

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item.

24. Future Meeting Dates and Agenda Items (TAB 17)

Presiding Officer Geren announced that the next Oversight Committee meeting is February 17, 2016, at 9:00 a.m.

25. Adjourn

MOTION:

There being no further business, Presiding Officer Geren entertained a motion to adjourn.

Motion was made by Dr. Rice and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

Meeting adjourned at 2:50 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH
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MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 5, CHIEF EXECUTIVE OFFICER REPORT
DATE:	FEBRUARY 8, 2016

As of this writing the Chief Executive Officer Report for the February 17, 2016, Oversight Committee will consist of the following items:

- Introduction of James (Jim) Willson, M.D., Chief Scientific Officer
- Action Items from November 19, 2015, Oversight Committee Meeting (see following memorandum)
- CEO Report Pursuant to Health & Safety Code § 102.260(c) (Continuing Progress and Merit of CPRIT's Programs in Prevention, Academic and Product Development Research) (see following memorandum)
- Prevention Funding (statutory requirement that no more than 10% of CPRIT awards may be used for cancer prevention and control programs during any year) (explanatory memorandum will be available on February 12)
- Report on "FY 2016 Grant Award Funds Available" (see following attachment)
- Program Funding Targets for FY2016 and Beyond (see following memorandum)

In addition, for your reference, copies of the CPRIT Activities Updates for December and January previously provided to you are included at the end of this tab. These are the reports provided to you in months in which the Oversight Committee does not meet.

Other topics may be added as warranted.

*****

CPRIT has awarded **992** grants totaling **$1.471 billion**

- 158 prevention awards totaling $155.4 million
- 834 academic research and product development research awards totaling $1.316 billion

Of the $1.316 billion in academic research and product development awards,

- 31.4% of the funding ($412.6 million) supports clinical research projects
- 26.0% of the funding ($342.6 million) supports translational research projects
- 23.4% of funding ($308.2 million) supports recruitment awards
- 15.8% of the funding ($208.4 million) supports discovery stage research projects
- 3.4% of funding ($44.4 million) supports training programs.

CPRIT has 11 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 2 Product Development Research
- 6 Prevention

CANCER PREVENTION & RESEARCH
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MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
Subject:	**ACTION ITEMS FROM NOVEMBER 19, 2015, OVERSIGHT COMMITTEE MEETING**
Date:	**FEBRUARY 10, 2016**

Summary:

This report updates the Oversight Committee on implementation of action items from the November 19, 2015, Oversight Committee meeting.

Discussion:

The Oversight Committee requested the CPRIT staff address several issues following the November 19, 2015, Oversight Committee meeting. This memo provides a summary for each item, its status, next steps, and assigned CPRIT staff members.

Prevention Awards 10% Statutory Cap Issue (Wayne Roberts, Heidi McConnell, Becky Garcia, Kristen Doyle)

CPRIT staff committed to developing a year-by-year analysis of final awards for all three programs to determine accurate funding history. This is to monitor compliance with the statutory limit restricting prevention grants to no more than 10% of funds available for all awards.

- Status: Funding history for Prevention, Academic Research, and Product Development Research Program is prepared for discussion at the February 17, 2016, Oversight Committee meeting. A separate memo in the Agenda Packet explains the problem and provides options for the Oversight Committee's consideration and discussion.

- Next Steps: This will be an action item for the Oversight Committee.

Research Programs Funding Targets for FY 2016 (Wayne Roberts, Margaret Kripke/James Willson, Michael Lang)

The issue was discussed but not resolved at November 19, 2015, meeting. I was directed to provide options to inform the discussion at subsequent regular or special Oversight Committee meetings. Based upon projected FY2016 grant awards for both the Academic Research and Product Development Research Programs, CPRIT program staff needs immediate near-term

direction from the Oversight Committee on February 17, 2016. Discussion on how to proceed with the long-term policy or approach will also occur.

- Status: CPRIT staff is finalizing options for FY2016 research funding allocation for Oversight Committee consideration and discussion at the February 17, 2016, meeting. Material related to the issue is included in the Agenda Packet.

- Next Steps: Deciding upon near-term options will be an action item for the Oversight Committee. This may entail setting one or more special meetings to address the near-term and long-term issues.

Program Presentation Material (Kristen Doyle, Program Staff)

The Oversight Committee requested that CPRIT's three programs clearly show how proposed awards meet the Oversight Committee's Program Priorities. Program Officers should provide this information when the Oversight Committee considers the grant recommendations. Generally, the Oversight Committee requested that the three programs follow a uniform format when presenting certain information about award recommendations and limit the use of acronyms.

- Status: The only funding recommendations at the February 17, 2016, Oversight Committee meeting are from the Academic Research Program. Dr. Kripke's memo explaining the award recommendations specifies the Oversight Committee's priorities addressed by the proposed grants.

- Next Steps: CPRIT staff will work together before the May Oversight Committee meeting to standardize the format for award recommendation material.

Analysis of Academic Research Program Recruitment Awards (Margaret Kripke/James Willson, Michael Brown):

CPRIT staff is working on gathering data related to recruitment awards, including the number of FTEs added with each recruitment award, additional funding (and grants) brought to Texas, and post-grant developments. The goal is to substantiate the recruitees' contribution to growing the life sciences infrastructure in Texas. Several larger and related staff projects will incorporate this information including: 1) significance report, 2) support material for use during the 85th Texas Legislature in January 2017, and 3) website redesign.

- Status: CPRIT staff is collecting these data. SRA International, our large award management contractor, has also been involved in discussions to provide additional information related to these efforts.

- Next Steps: Staff will provide periodic reports to the Oversight Committee on these efforts.

Internal Audit (Heidi McConnell and Vince Burgess)

The Audit Subcommittee requested that CPRIT staff prepare a quarterly reporting mechanism on internal audit recommendation implementation. The subcommittee also requested that an internal audit focus on Information Technology security with annual updates.

- Status: Development of a quarterly reporting mechanism is complete. CPRIT staff used the quarterly reporting mechanism for the most recent presentation to the Audit Subcommittee. CPRIT staff will include IT security when setting future internal audit annual plans.

Compliance and Other Reporting (Vince Burgess)

The Oversight Committee requested that the Chief Compliance Officer evaluate CPRIT's reporting requirements for grantees to determine necessity and applicability (i.e., why is the report needed and is it still needed if the original purpose of the report has been met?)

- Status: The report is complete and provided in the Agenda Packet. Mr. Burgess presented the report to the Board Governance Subcommittee and the Audit Subcommittee.

- Next Steps: Discussion at the February 17, 2015, Oversight Committee meeting.

Recruitment Awards – Consider Deadline for Accepting Award (Margaret Kripke/James Willson)

The Oversight Committee asked whether CPRIT should consider establishing a deadline to accept recruitment awards.

- Status: Program staff is considering this issue. Some pros and cons for establishing a fiscal year-end deadline for accepting recruitment and product development research awards are discussed briefly in the memo regarding Prevention Program Funding in your Agenda Packet.

- Next Steps: CPRIT staff will continue to work on a recommendation for Oversight Committee consideration.

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MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER**
Subject:	**FY2015 REPORT ON MERIT AND PROGRESS OF PROGRAMS PURSUANT TO TEXAS HEALTH & SAFETY CODE § 102.260(C)**
Date:	**FEBRUARY 10, 2016**

Summary

In FY2015, the Oversight Committee approved 134 grants totaling $274,260,908.[1] Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each research program. CPRIT's Academic Research Program, Prevention Program and Product Development Research Program showed progress and merit in fiscal year 2015 (FY2015).

This report provides an overview illustrating the progress made in advancing CPRIT's mission to create and expedite innovation in cancer research and cancer prevention. Aligning program activities with the program priorities adopted by the Oversight Committee is a good gauge of progress and merit. This report highlights each program's implementation of the FY2015 program priorities. CPRIT's FY2015 *Annual Report* and quarterly *Achievements Report* provide more information on CPRIT awards.

With regard to progress made by individual grant projects within each of CPRIT's three programs, Texas Administrative Code § 703.21 requires all CPRIT grantees to submit progress reports at least annually. Outside experts evaluate these progress reports to ensure that the grantee has made sufficient progress and should continue work under the grant. To the extent that an expert reviewer determines that a grant project is not making sufficient progress, CPRIT may take a number of actions, including contract termination. CPRIT did not terminate any award during FY2015 for lack of sufficient progress.

[1] Unless specifically noted, all grant awards and amounts discussed in this report reflect the awards approved by the Oversight Committee in FY2015 that are either under contract with a grantee or the grantee has not declined the award as of the date of this memo.

Academic Research Program

CPRIT's Academic Research Program supports innovative and meritorious projects that are discovering new information about cancer that can lead to prevention, early detection, and cures; translating new and existing discoveries into practical advances in cancer diagnosis and treatment; and increasing the prominence and stature of Texas in the fight against cancer.

In FY2015, CPRIT's Academic Research Program awarded 51 Individual Investigator Research Awards, 16 High Impact-High Risk research grants, 6 Core Facilities Support Awards, 2 Multi-Investigator Research Awards, and 17 recruitment awards to Texas institutions. In addition, the Product Development peer reviewers recommended 20 applications from 10 academic research institutions for Early Translational Research Awards (ETRAs).[2] The total amount of Academic Research awards approved by Oversight Committee in FY2015 and under contract was $189,327,986.

Academic Research Program Priorities

The Oversight Committee adopted the following FY2015 program priorities for the Academic Research Program:

- A broad range of innovative, investigator-initiated academic research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Infrastructure development.

This was the first full year that the Oversight Committee's program priorities have been in place. These priorities have influenced Requests for Applications (RFAs) and funding for the Academic Research Program. For example, the number of grants dedicated to childhood and adolescent cancers has increased from 4% to 13% after the Oversight Committee's decision to prioritize rare and intractable cancers, including childhood cancers. Similarly, the number of Academic Research grants awarded for prevention and early detection research has increased from 13% to 17%.

Seventeen recruits accepted positions at Texas institutions, for a total of $49 million in recruitment grant awards. CPRIT is building a critical mass of cancer researchers in Texas by

[2] The Product Development Research Program issued the RFA soliciting the proposals ultimately approved for ETRA grants in FY2015. The Academic Research Program awarded previous ETRAs under its program with its reviewers. After discussion with CPRIT staff, the Oversight Committee decided that although ETRAs have a place in both the Academic Research Program and the Product Development Program, it is appropriate to classify the awards under the Academic Research Program.

supporting recruitment of cancer scientists and clinicians as cancer research scholars to academic institutions in Texas. Since its inception through August 31, 2015, CPRIT has supported the recruitment of 95 outstanding cancer researchers to 14 academic institutions throughout Texas. This program has been highly successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in this field, which ultimately benefits the life sciences infrastructure in Texas.

Prevention Program

CPRIT's Prevention Program supports effective, evidence-based prevention programs to underserved populations in the state. Prevention Program grants help Texans reduce the risk of getting cancer, identify cancers earlier, and assist people in finding cancer treatment. These efforts reduce the burden of cancer in Texas. There were 70 Prevention Program projects active throughout Texas in FY2015. The Oversight Committee approved 16 new grants during the fiscal year totaling $27,890,646.

The Prevention Program reached an important milestone in FY2015: CPRIT grantees have provided more than 2.6 million education and clinical prevention services since 2010. These services reach all Texas counties and include tobacco cessation, genetic testing and counseling, vaccinations and survivor care services. Texans received more than 1.4 million clinical prevention services. Screenings and diagnostics for breast, cervical, colorectal, and liver cancer account for more than 628,400 of the clinical services. The CPRIT-funded screenings identified 51,708 abnormal results, detected 4,063 cancer precursors, and found 1,778 cancers. More than 226,000 recipients received their first cancer screenings from CPRIT projects. These numbers highlight the impact CPRIT has in Texas communities.

In addition to the impact on the health of people in Texas, the Prevention Program grants also improve the healthcare system and foster greater collaborations. Health system improvements include reducing wait times for diagnostic testing, reducing the number of people lost to follow-up, implementing patient reminder systems, enhancing electronic medical records, and training a cadre of community health care workers to help educate and navigate people through the system. These grants stimulate greater collaboration among academic institutions, community organizations, and clinics; 95% of the academic institutions receiving a Prevention Program grant are collaborating with a non-academic organization.

<u>Prevention Program Priorities</u>

The Oversight Committee adopted the following FY2015 program priorities for the Prevention Program:

- Prioritize populations and geographic areas of greatest need, greatest potential for impact;
- Focus on underserved populations; and
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist.

Six RFAs were released in FY2015 including one on Colorectal Cancer Prevention Coalitions and another on Cancer Prevention and Navigation to Clinical Services. Due to the timing of approval of the program priorities by the Oversight Committee, the FY2015 RFAs do not explicitly reflect the program priorities. Nonetheless, upon review of the active projects, 21 prevention grants prioritize population and geographic areas of greatest need, 62 grant projects currently focus on underserved populations, and 25 grants increase targeting of efforts to areas where significant disparities in the state exist.

Product Development Research Program

CPRIT's Product Development Research Program funds innovative and scientifically meritorious product development projects with the potential of translating research discoveries into commercial products that can benefit cancer patients. During FY2015, the Oversight Committee approved six Product Development Research awards totaling $57,042,276.

CPRIT has 19 active company grants in FY2015. Five CPRIT-funded company projects conducted clinical trials in FY2015, reaching cancer patients in Texas with innovative, early stage treatments. The Product Development Research program benefits not only cancer patients, but like CPRIT's recruitment grants, the Product Development Research awards are an important component in building the life sciences infrastructure and community in Texas.

Since 2010 through August 31, 2015, CPRIT companies raised $911 million in follow-on funding from other investors. During FY2015, three CPRIT-funded companies announced plans for initial public offerings (IPOs). One IPO occurred in June and another took place in September. In addition, NASDAQ listed ESSA for the first time. These follow-on investments and activities testify to the quality of the CPRIT-funded projects and CPRIT's review process.

<u>Product Development Research Program Priorities</u>

The Oversight Committee adopted the following FY2015 priorities for the Product Development Research Program:

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market;
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace; and
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention.

The six companies funded in FY2015 work in Texas to bring important products to market. Three companies awarded grants in FY2015 relocated to Texas: Armada Pharmaceuticals (renamed Formation Biologics, from Toronto, Canada), Immatics U.S. (from Germany), and Medicenna (from Vancouver, Canada). Five of the six company projects approved in FY2015 have collaborations with academic institutions in Texas, promoting the translation of research into Texas-based companies. In addition, two of these awards fulfill the priority for developing tools and technologies of special relevance to cancer research and treatment. One project funds research and development for a test to assess the risk of ovarian cancer prior to surgery. Another project funds clinical research for a device that restores bladder function and improves quality of life for cancer patients suffering complications from surgical resection and radiotherapy.

Conclusion

CPRIT's three programs show merit and progress and should continue operations. The work conducted under the purview of CPRIT's programs is part of an iterative cycle with observations emerging from the laboratory making their way to the public and back again to the laboratory. Essential players in this cycle are basic scientists, physician scientists, clinical researchers, product development entrepreneurs, public health professionals, health care providers, patients, community organizations, early stage companies, and research institutions across Texas.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	PREVENTION PROGRAM FUNDING
DATE:	FEBRUARY 10, 2016

Summary

The total amount of prevention grants awarded by CPRIT exceeds the statutory limit by approximately $2.77 million. Texas Health & Safety Code §102.203(e) restricts the money awarded for cancer prevention programs to not more than 10 percent of the money awarded during any year. Several options are available for recalibrating the prevention grant spending to comply with the statutory limit. These options include taking a one-time $2.77 million reduction in prevention program awards in one fiscal year, spreading the reduction over the several fiscal years, or retroactively reducing awarded amounts via contract amendments. The Oversight Committee should discuss these options with Chief Prevention Officer Dr. Becky Garcia at the February 17, 2016, meeting.

Discussion

Texas Health & Safety Code § 102.203(e) limits the amount of grant funding that may be obligated for cancer prevention grants each year, stating, "Not more than 10 percent of the money awarded under this subchapter may be used for cancer prevention and control programs during any year." At the beginning of each biennium, CPRIT staff uses the General Appropriations Act's calculation of appropriated amounts available for grant awards to determine the allowable prevention awards amount for the fiscal year.

As part of an ongoing analysis of available funding, CPRIT staff discovered that the practice of using the appropriated amounts figure to calculate the grant funds available for prevention awards unintentionally results in the accumulation of an overage above the statutory limit. This happens because the statute calculates the limit based on the "money awarded" during the year. CPRIT's statute uses the terms "awarded" or "awarding" to refer to grant funds committed under a contract. For example, Health & Safety Code § 102.255(a) and (b) dictate that, "The oversight committee shall negotiate on behalf of the state regarding the ***awarding***, by grant, money under this chapter. Before ***awarding*** a grant under Subchapter E, the committee shall enter into a written contract with the grant recipient…"

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Since September 1, 2009, CPRIT has awarded $142,135,920 in prevention grants. CPRIT has awarded $1,326,968,527 in total for grants to entities, organizations, and institutions across the state. An initial comparison between the prevention grant amounts and the total grant funds awarded indicates that the prevention grants top the 10% statutory cap by $9,439,067. However, CPRIT staff determined that prevention grantees did not expend the full amount obligated by contracts for FY 2011 – FY 2013. As a result, $6.6 million of the overage naturally resolved itself, leaving $2.77 in excess of the 10% limitation.

The inconsistencies between the Texas Legislature's biennial appropriations amount for grant awards and the actual award amounts are attributable to three factors. The first factor, post-fiscal year award declinations in the Research Program, is responsible for most of the Prevention Program overage. Each fiscal year, the Oversight Committee approves grant recommendations for some academic research and/or product development projects that the grant applicants ultimately decline prior to contract execution. The declination may occur in the same fiscal year that the Oversight Committee approved the grant. When this happens, CPRIT does not count the declined award amount toward the $300 million annual limit on grant awards and, if possible, uses the released funds for another award in the same fiscal year.

If a declination occurs after the fiscal year ends, CPRIT subtracts the unobligated award from the total amount awarded in the fiscal year that the Oversight Committee approved the grant recommendation. However, CPRIT is unable to re-award those funds to another project. As a result, prevention grants awarded during the fiscal year may represent 10 percent of the total amount appropriated for grant awards that the Oversight Committee *approves* during a fiscal year. However, post-fiscal year declinations by research awardees reduce the total amount *awarded* (i.e. committed by contract) for the fiscal year. If all academic research and product development research award applicants approved for grants executed award contracts, then CPRIT would not be facing this problem.

The second factor is increases in the operating budget to support the additional grant award processes as the three programs were ramping up in FY 2011 and FY 2012. While the increases in the operating budgets reduced the overall amount of the funding available for grant awards, the agency used the appropriated amount of funds for the prevention program and did not recalibrate the available funding for prevention grants.

The moratorium in FY 2013 is another contributing factor to the overage. The Oversight Committee approved some prevention grants before the moratorium stopped Oversight Committee consideration of any other grant recommendations for the remainder of FY 2013. As a result, prevention grants were slightly overrepresented in the total awards for the year.

Options to Address Overage

CPRIT should take steps to comply with the statutory directive and resolve the remaining overage. CPRIT staff has identified three options to realign prevention grant spending to address the overage:

Option 1: Realignment by One-Time Program Funding Reduction

Reduce the total allowable Prevention Program funding in one fiscal year by $2.77 million to account for the Prevention Program funding overage. This option is reflected on the attached "Prevention Grant Funding History and Adjustment Options" with the one-time reduction occurring in FY 2019. CPRIT used FY 2019 in the Option 1 Table for illustrative purposes.

Taking a one-time reduction in any year has the disadvantage of slowing CPRIT's rebounding momentum following the FY 2013 funding moratorium. The Prevention Program has steadily built up the number of applications received and grants awarded after FY 2013. The geographic coverage of counties within the state was at 64% after the moratorium and to date we have increased the coverage to 92%. We are seeing the growing momentum with this cycle's applications due March 3. Twenty-nine prospective applicants have started grant applications this cycle compared to 10 starts the same number of weeks out for the past cycle. Dr. Garcia and Ramona Magid visited several parts of the state encouraging applications; some of these new applications are a direct result of those efforts. Making the $2.77 million reduction in FY 2016 directly affects the projects that CPRIT's reviewers will evaluate this year. However, the benefit of making the reduction now is that CPRIT immediately recalibrates Prevention Program funding to fall within the statutory limit without affecting previous projects.

Even if it does not occur this fiscal year, a one-time reduction may negatively affect CPRIT's efforts to rebuild momentum and demonstrate the Prevention Program's impact across the state. Nevertheless, putting off the reduction until FY 2017 or later means that CPRIT remains out of compliance with the statute for a longer period if the overage is not naturally resolved.

Option 2: Incremental Realignment by Multi-Year Program Funding Reductions

Reduce the total allowable Prevention Program funding by spreading the $2.77 million overage across the next several years. The attachment reflects this option under Option 2 on the attachment and spreads the overage evenly among FY 2016 – FY 2019 for illustrative purposes.

The multi-year reduction minimizes the impact on future prevention projects and allows more time for there to be a natural resolution of the remaining overage resulting when prevention grantees do not expend the full amount obligated by contracts ending in FY 2016. Although the $700,000 - $1.35 million reduction (depending upon the number of years selected) per year is not insignificant, it is at a level that allows CPRIT to maintain nearly the full level of prevention

services. The disadvantage to incremental realignment is that CPRIT cannot fully resolve the noncompliance issue for several years.

Option 3: Retroactive Realignment by Contract and Fiscal Year

CPRIT amends active FY 2013 – FY 2016 prevention contracts to reduce prevention grant funding awarded in the fiscal year so that the total prevention amount equals to 10% of the total grant funds awarded in that fiscal year. This option immediately addresses the problem and is consistent with the statutory directive to assess the 10% limit each year. However, this is the most disruptive and potentially destabilizing option. For active contracts, retroactively reducing grant award amounts significantly disorders grantee budgets already approved by CPRIT and affects grantees' ability to meet their goals and deliver the services proposed and approved through the peer review process.

Actions Going Forward to Prevent Future Overages

CPRIT staff will closely track the proportion of prevention grant funds relative to the total amount of grant funds obligated by contract each fiscal year and update the Oversight Committee quarterly. We will also work with the legislature to seek clarity on the calculation of the 10% limit. Unless the legislature amends the statutory provision to tie the 10% funding limit to something other than awarded funds and/or changes the assessment by year, CPRIT staff will calculate the anticipated amount available for prevention grants at an amount that leaves some cushion to account for declinations. This means that Prevention Program grant funding will be less than the full amount authorized by statute.

Another option to prevent the overage issue from occurring in the future is establishing a time limit for grantees to accept a grant award. An acceptance deadline provides some level of additional certainty for calculating the awarded amount in a fiscal year. However, this option will not entirely address the problem created by post-fiscal year declinations unless the deadline for accepting the award coincides with the end of the fiscal year (as opposed to a fixed number of months that may extend past the end of the fiscal year.) Creating an arbitrary August 31 deadline for accepting grant awards creates problems for potential recruitment grantees and product development grantees approved for awards at the August Oversight Committee meetings, and potentially for those approved at the May Oversight Committee meetings. Grants that may otherwise be accepted by the potential grantees could be cancelled simply because there is not enough time for CPRIT and the grantee to negotiate a contract or for a potential recruitment to make a relocation decision by the end of the fiscal year.

PREVENTION GRANT FUNDING HISTORY AND ADJUSTMENT OPTIONS

Appropriation Year	Total Legislative Appropriations	Appropriations Available for Grant Awards (Less Operating Costs)	Contracted Prevention Grants	Prevention Grants Contracted (Percent)	Total Grant Awards Contracted/Pending Contract	Contracted Prevention Grants [Adjusted]	Contracted Prevention Grants (Percent) [Adjusted]	Total Grant Awards Contracted [Adjusted]
2010	$ 225,000,000	$ 216,163,477	$ 21,689,774	10.0%	$ 216,122,104	$ 21,689,774	10.0%	$ 216,122,104
2011	$ 225,000,000	$ 213,226,330	$ 21,699,312	10.4%	$ 208,843,129	$ 19,975,723	9.6%	$ 207,119,540
2012	$ 300,000,000	$ 281,408,334	$ 28,932,838	10.9%	$ 265,334,572	$ 25,520,792	9.7%	$ 261,922,526
2013^	$ 300,000,000	$ 280,409,352	$ 13,576,658	12.9%	$ 105,493,808	$ 12,049,591	11.6%	$ 103,966,741
2014	$ 300,000,000	$ 279,507,332	$ 28,346,692	11.2%	$ 253,834,580	$ 28,346,692	11.2%	$ 253,834,580
2015**	$ 300,000,000	$ 279,308,900	$ 27,890,646	10.1%	$ 277,340,334	$ 27,890,646	10.1%	$ 277,340,334
		$ 1,550,023,725	$ 142,135,920	10.7%	**$ 1,326,968,527**	$ 135,473,218	10.2%	$ 1,320,305,825

Prevention should have been	**$ 132,696,853**		
Contracted	**$ 142,135,920**	**Adjusted Contracted**	**$ 135,473,218**
Overfunding	**$ (9,439,067)**	**Adjusted Overfunding**	**$ (2,776,365)**
Unspent Prevention Funds Adjustment	**$ 6,662,702**	**Adjusted Prevention Funding**	**$ 132,696,853**
Adjusted Overfunding	**$ (2,776,365)**		

OPTION 1

		Projected Funds Available for Prevention (10%)	Adjustment to Prevention Grant Funds Forward	Adjusted Prevention Grants (Percent)	Projected Grant Awards Contracted
2016	$ 300,000,000	$ 27,965,885	*$ 27,777,778*	10.0%	$ 277,777,778
2017	$ 300,000,000	$ 27,965,885	*$ 27,777,778*	10.0%	$ 277,777,778
2018	$ 300,000,000	$ 27,965,885	*$ 27,777,778*	10.0%	$ 277,777,778
2019*	$ 300,000,000	$ 27,965,885	*$ 25,001,413*	9.1%	$ 275,001,413
			$ 243,807,965	10.0%	$ 2,435,303,274

OPTION 2

		Projected Funds Available for Prevention (10%)	Adjustment to Prevention Grant Funds Forward	Adjusted Prevention Grants (Percent)	Projected Grant Awards Contracted
2016	$ 300,000,000	$ 27,965,885	*$ 27,083,687*	9.8%	$ 277,083,687
2017	$ 300,000,000	$ 27,965,885	*$ 27,083,687*	9.8%	$ 277,083,687
2018	$ 300,000,000	$ 27,965,885	*$ 27,083,687*	9.8%	$ 277,083,687
2019*	$ 300,000,000	$ 27,965,885	*$ 27,083,687*	9.8%	$ 277,083,687
			$ 243,807,965	10.0%	$ 2,435,303,274

* Assumes 8 fiscal years of $300 million funding and 2 fiscal years of $225 million funding.

^ State leadership imposed moratorium on CPRIT grant award processes in effect after 12/17/12.

** All grant awards announced during FY 2015 have not completed contracting.

2-17

FY 2016 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / PD Research	Prevention Percentage Based on Available Award Appropriations	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 28,325,035	$ 254,925,317		$ 16,749,648	$ 300,000,000
Unexpended Bond Proceeds Carry Forward		$ -			$ -
Unexpended Balance Carry Forward		$ -			
Approved Adjustment to Operating Costs		$ (621,952)		$ 621,952	
Unapproved Adjustment to Operating Cost		$ -		$ -	
Appropriations Transfer to DSHS		$ (2,969,554)		$ 2,969,554	
Adjusted Appropriations	$ 28,325,035	$ 251,333,811		$ 20,341,154	$ 300,000,000
Total Available for All Grants			$ 279,658,846		
Calculated 10% for Prevention Grants of Total Available Grant Funding			$ 27,965,885		
Adjustment for 10% Prevention Grants Limit	(359,150)	$ 359,150			
Revised Adjusted Appropriations	$ 27,965,885	$ 251,692,961		$ 20,341,154	$ 300,000,000
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 27,965,885	$ 251,692,961			$ 279,658,846
Announced Grants					
9/10/15 Rsch Recruitment Awards		$ 17,700,000			
11/19/15 Rsch Recruitment Awards		$ 16,000,000			
11/19/15 Rsch Awards-IIRA		$ 34,744,442			
11/19/15 Rsch Training		$ 14,966,408			
11/19/15 PD Awards		$ 20,000,000			
11/19/15 Prevention Awards	$ 13,247,742				
Announced Grant Award Subtotal	$ 13,247,742	$ 103,410,850	$ -		$ 116,658,592
Available Funds Post November 2015	$ 14,718,143	$ 148,282,111			$ 163,000,254
Pending Grants					
Pending Recruits for Feb 2016 OC Meeting		$ 34,000,000			
Pending Recruit-Feb 2016 OC Mtg (Declined)		$ (2,000,000)			
Pending Recruit-Feb 2016 OC Mtg (Declined)		$ (6,000,000)			
PD Grant Proposal Pipeline		$ 50,221,088			
Pending Award Subtotal	$ -	$ 76,221,088			$ 76,221,088
Total Potential Grant Funding Committed		$ 179,631,938			
Available Funds as of January 29, 2016	$ 14,718,143	$ 72,061,023			$ 86,779,166

Operating Budget Detail	
Indirect Administration	$ 3,003,133
Grant Review & Award Operations	$ 14,368,467
Subtotal, CPRIT Operating Costs	$ 17,371,600
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	20,341,154

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
Subject:	**PROGRAM FUNDING TARGETS FOR FY2016 AND BEYOND**
Date:	**FEBRUARY 10, 2016**

Summary:

The Oversight Committee (OC) discussed setting targets, either by dollar or by percentage amounts, for Academic Research and Product Development Research programs. Prevention Program funding is limited by law to no more than 10% of funds awarded during any year. This memo identifies two steps; the first is to establish long-term targets tied to previously adopted OC priorities and statutory purposes. The second is to establish a *temporary*, short-term target for use during the remainder of FY2016 due to anticipated over-demand of CPRIT funds.

Discussion:

To date, the Oversight Committee has not established funding targets for the Academic Research and Product Development Research programs or otherwise split funding between the two programs. Until now, targets have not been an urgent need since sufficient money has been available to fund all recommendations made by the Scientific Review Council and the Product Development Review Council. However, the Oversight Committee has expressed a desire to set targets to establish a transparent policy for staff to use in issuing the types and number of Requests for Applications (RFAs) and for peer review evaluation of applications. In addition, based on projections from the two programs, it is unlikely that sufficient funds will be available to fund all recommendations from the review councils in FY2016.

Through November 2015, academic research grants account for 79.5% of total research funding, while product development grants make up the remaining 20.5% of research portfolio. The disparity in funding between the two programs occurred largely due to three factors. First, the Commercialization/Product Development Program started awarding grants later than the Academic Research program. Second, the Academic Research program receives far more applications than the Product Development Research program. This is a function of the number of institutional researchers applying compared to companies. Finally, the Academic Research Program releases a greater number of RFAs,

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The Oversight Committee formally established program priorities for the first time in November 2014. In addition, although awards were made in compliance with state law, RFAs and funding recommendations were not linked to the specific statutory purposes in Health & Safety Code § 102.002. The Oversight Committee has expressed its interest in incorporating both the Oversight Committee's program priorities and the statutory priorities into the program targeting exercise, which is also envisioned as a standing agenda item for discussion at Oversight Committee meetings.

The issue of establishing funding targets for Academic Research and Product Development Research may be divided into two separate but related steps: near-term versus far-term target setting. Each is discussed below.

Far-Term Target Setting

Presiding Officer Geren suggests convening at least one special work session at which the discussion is focused solely on long-term target setting between the two programs. The work session allows the new Chief Scientific Officer and Chief Product Development Officer to explain the effects of various options on their programs. Due to existing scheduled program peer review, Oversight Committee meetings, and a tentatively planned state informational tour concerning CPRIT activities, suggested weeks are:

- April 18-22
- May 16-20 (in conjunction with existing May 17 OC meeting)
- Anytime in June except June 1-10

Near-Term Target Setting

Due to the funding demand that is likely to exceed available grant awards in FY2016, I recommend that a temporary one-time target be set for prioritizing the competing interests. This would not be the far-term policy but a response to the budget situation described below.

As indicated in the table "FY 2016 Grant Awards Funds Available," after accounting for research awards previously made and known recommendations coming forward from the review councils, $66,061,023 is available for the remainder of the year for Academic Research, which includes research projects and recruitments. The spreadsheet accounts for the maximum amount for Product Development Research ($50,221,088 in the pipeline and $20.0 million awarded) for FY 2016.

Not included in the spreadsheet is at least $70.3 million in research projects. Since the RFA for recruitments is continuously open, additional FY2016 recruitment requests will continue to be submitted.

A conservative estimate based on the above figures is that we are $4.2 million short of expected demand. Options to accommodate this deficit will be discussed on February 17.

The table "FY2016 Near-Term Temporary Program Targets" outlines three of many possible target options. Historically, the award-funding split between the *three* programs is: Academic Research, including recruitment (70%); Product Development Research (20%); and Prevention (10%). Option One holds the FY2016 program allotments at the historical split of 70-20-10. Option Two allots the FY2016 program funding based on a 60-30-10 split. Option Three is a halfway point between the first two – 65-25-10.

Additional information concerning how Academic Research and Product Development Research may accommodate these two options along with additional items to consider will be provided at or before the meeting.

For now, several issues to consider are:

- Some prevention funds may be transferred and be available to research programs in FY2016, depending upon the Oversight Committee's decision to address Prevention's overfunding in previous years.
- Not all Product Development recommendations in the pipeline may pass due diligence. The Product Development Review Council is scheduled to consider due diligence reports for the five pending applications in late March.
- Historically, 24% of recruits decline. If this percentage holds true for FY2016, then the $67.7 million already awarded or recommended for recruitment grants this year may decline by approximately $11.5 million. One recruit has already declined.
- The Oversight Committee may wish to close the recruitment RFAs to new applications for the remainder of FY2016 to avoid exacerbating the potential funding deficit or take other actions such as deferring decisions on recruits after the May meeting to a special September OC meeting in FY2017.

FY2016 Near-Term Temporary Program Targets

	Option One 70-20-10 Split	Option Two 60-30-10 Split	Option Three 65-25-10 Split
Amount Available for All Grant Awards	$279,658,845	$279,658,845	$279,658,845
Historical Percent Split for Each Program			
Academic Research: 70%			
Product Development Research: 20%			
Prevention: 10%			
Less: 10% Statutory Limit for Prevention	(27,965,885)	(27,965,885)	(27,965,885)
Net Amount Available for Two Research Programs	$251,692,961	$251,692,961	$251,692,961
Target for Academic Research	195,761,192	167,795,307	181,778,249
Target for Product Development Research	55,931,769	83,897,654	69,914,711
Awarded Grants thru February 17	$129,410,850	$129,410,850	$129,410,850
Academic Research Total	109,410,850	109,410,850	109,410,850
Projects	49,710,850	49,710,850	49,710,850
Recruitments (less 2 declinations)	59,700,000	59,700,000	59,700,000
Product Development Research	20,000,000	20,000,000	20,000,000
Amount Remaining for Awards Post 2-17-16	$122,282,111	$122,282,111	$122,282,111
Estimated in Pipeline	120,500,050	120,500,050	120,500,050
Academic Research	70,278,962	70,278,962	70,278,962
Projects (May); not peer reviewed	70,278,962	70,278,962	70,278,962
Recruitments (May); peer reviewed, not recommended	0	0	0
Product Development Research (May); thru peer review, in due diligence	50,221,088	50,221,088	50,221,088
Projected Balance Including Pipeline	$1,782,061	$1,782,061	$1,782,061
FY 2016 Projected Balance Per Split			
Academic Research	16,071,380	(11,894,505)	2,088,437
Product Development Research	(14,289,319)	13,676,566	(306,377)
Transfer to Academic from Product Development Research Resulting in Academic Development Deficit of		1,782,061	
Transfer to Product Development from Academic Resulting in Product Development Deficit of	1,782,061		

Annual Recruitment Award Statistics

Fiscal Year	Grants Announced/ Pending ($)	Grants Declined ($)	Percentage Declined ($)	Number Announced/ Pending	Number Declined	Percent Declined (#)
2010	$ 19,999,705	$ -	0%	9	0	0%
2011	$ 54,000,000	$ 9,000,000	17%	17	4	24%
2012	$ 92,531,402	$ 28,750,000	31%	24	10	42%
2013^	$ 52,339,550	$ 13,500,000	26%	19	7	37%
2014	$ 65,339,259	$ 11,000,000	17%	22	5	23%
2015	$ 67,000,000	$ 18,000,000	27%	22	5	23%
2016*	$ 67,700,000	$ 8,000,000	12%	18	2	11%
TOTAL	**$ 418,909,916**	**$ 88,250,000**	**21%**	**131**	**33**	**25%**

^ State leadership imposed grant award moratorium in effect after 12/17/12.

* Grant year in progress.

Identified Program Funding Reductions

Based on the latest information available (2-15-16) there is no annual deficit based on projections, but a surplus of nearly $1.8 million. However, depending upon the split used for FY2016, one program could be overfunded and the other underfunded. It is possible to adjust the mix so that both programs are fully funded based upon current projections of academic research grants, excluding future recruitments. The amount of recruitment applications remaining is unknown.

Identified program adjustments to accommodate the scenarios include the following.

Academic Research

- Reduce the number of Core Facilities Support Awards (CFSA) grants in May to 2, generating savings of around $20M, and the number of Multi-Investigator Research Awards (MIRAs) to 3, generating savings of another $15M from the projected amount of $70.3M. Any CFSAs or MIRAs approved by the SRC in excess of these numbers could be held until the August OC meeting, at which time a funding decision for these could be made based on funds available.
- Leave intact the High Impact-High Risk (HIHR) awards, which represent a small amount of the total funds ($3M) and leaves $20M available for either product development or academic research awards but most likely for recruitment awards for the remainder of the year.
- Based upon historical trends, 24% of recruits decline leaving on average 20% of the award amount unspent. Two have already declined. Based on this trend, another $5.5 million may be available by August.
- Close the recruitment RFA for the remainder of the year
- Pro rata reduction to all recommended awards
- Instruct Scientific Review Council to use a higher funding threshold to reduce the number of applications recommended

Product Development Research

- One or more of the 5 projects ($50.2 million) recommended by the Product Development Review Council may not pass due diligence (projects are (millions): $2.5, $4.9, $6.0, $17.9, and $18.9)
- Authorize staff to review the budgets of the 5 recommended projects and Ruga to identify cost reduction opportunities. The larger projects represent greater cost reduction possibilities. Cost reductions could have other impacts, e.g., slower development, increased risk. It is doubtful $14 M in budget savings solely thru project cost reduction is possible.
- Delay funding one or more projects.

Prevention

Depending upon the resolution of the Prevention 10% cap issue, about $882,000 to $2,776,000 could be transferred from Prevention to the two Research programs.

Prevention awards of $13,247,742 were approved for the first cycle of FY2016, leaving a balance of $14,718,143 for the second cycle of awards. Reducing the available funds now by the overage would leave $11,940,778 for the reminder of FY2016, a 19% cut in the second cycle.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – JANUARY 2016
DATE:	FEBRUARY 2, 2016

Topics in the memo include: the upcoming Oversight Committee and subcommittee meetings; CPRIT staffing; legislative and related briefings; the President's Moonshot cancer initiative; Compliance, Program, and Operations updates; and staff presentations and meetings.

Preparation for February 17 Oversight Committee Meeting

The Oversight Committee is scheduled to meet February 17 at **9:00 a.m.** in the Capitol Extension. **Please note the earlier start time for this meeting.** The final agenda for the Oversight Committee meeting will be posted by February 9; a tentative agenda is attached to this update. We plan to distribute the agenda packet to Oversight Committee members electronically by COB February 10. Copies of the agenda packet will be available at the February 17 meeting.

Major agenda items that will require Oversight Committee action include recruitment award recommendations, approval of an internal auditor services contract, consideration of a settlement with Peloton Therapeutics, and adopting several changes to CPRIT's administrative rules. Other important items that do not require Oversight Committee action include the presentation of annual reports by the University Advisory Committee and the Advisory Committee on Childhood Cancer, the on-going review of CPRIT's award funds, Public Information Act and Texas Open Meeting Act training, and the CEO's annual performance evaluation.

You will receive an email from CPRIT by February 4 with a link and password to access the PIC's recommendations for recruitment awards via the grant award portal. The portal has supporting documentation regarding the award recommendations, including an award slate summary, the applications, CEO affidavits, and grant pedigrees.

As previously reported, I am seeking feedback on ways to improve the Oversight Committee quarterly meetings, the subcommittee process, and staff communications. My goal is to ensure that members' time spent on CPRIT activities is as effective and meaningful as possible. In

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addition to talking about this internally with staff, to date I have discussed this with four Oversight Committee members. I am in the process of scheduling individual calls to talk with all members.

Personnel Changes and Job Openings

Newly announced Chief Scientific Officer Dr. James "Jim" Willson will begin work on March 1. Dr. Kripke will remain on staff through March 16 to complete the academic research peer reviews occurring March 9-16. Dr. Willson plans to attend the February 17 Oversight Committee meeting.

CPRIT currently has 32 authorized full-time equivalent (FTE) positions all of which are filled with either permanent or temporary contract personnel. An Administrative Assistant and a Grant Accountant position were reposted through January 22. In the interim, both are filled by temporary contract employees.

Legislative and Related Briefings

Kristen Doyle and I met with three legislators or their staff in January: Representative John Zerwas (January 21), Senator Nelson's staff (January 21), and Senator Lois Kolkhorst (January 26). We updated them on CPRIT's activities.

I am scheduled to meet with Representative Paul Workman on February 9 to provide an overview of CPRIT and its activities.

White House Cancer Moonshot Task Force

In his State of the Union address, President Obama called for a moonshot initiative to eliminate cancer. The recently established Cancer Moonshot Task Force's announced priorities are to "focus on making the most of Federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care." Dr. Kripke and I have reached out to our federal contacts to provide any assistance to the task force and insights gained from Texas' bold plan to address cancer. To that end, we have invited Vice President Biden to join us on "Halfway Point" tour around Texas in April.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

A summary of delinquent/missing reports is produced by CPRIT's grant management system (CGMS) every week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities and receives approximately 550 grantee reports each month.

As of the most recent CGMS report (January 25, 2016), 16 required grantee reports from 9 entities have not been filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

FSR Reviews

CPRIT's Grant Compliance Specialists have performed 152 second level reviews of grantee Financial Status Reports (FSRs) during the month of January. Over 1,000 second level reviews have been performed during FY 2016. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Twenty-five desk reviews were performed during the month of January, bringing the FY 2016 year-to-date total to 127 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission.

On-site Reviews

Grant compliance staff performed three on-site reviews during the month of January. No issues were identified during these reviews. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year. During the month of January, five grantees submitted supporting documentation to fully remediate audit findings. Grant compliance specialists continue working with eight grantees towards resolution of outstanding audit findings.

Scientific Research Program Update

16.4 and 16.5-6 Recruitment Applications to be Considered by PIC and Oversight Committee

Twelve applications were submitted in response to requests for applications for recruitment cycles 16.4 - 16.6. The applications were reviewed by the Scientific Review Council (SRC) on November 12, 2015 (Cycle 16.4 applications) or January 14, 2016 (Cycles 16.5 and 16.6 applications.) Eight applications from cycles 16.4 – 16.6 were recommended for funding by the SRC for a total of $34 million.

The eight recommendations include four applications for Recruitment of Established Investigators (REI), one for Recruitment of Rising Stars (RRS), and three for Recruitment of First-Time, Tenure-Track Faculty Members (RFT). The PIC considered the proposed awards at its meeting on February 2 and have recommended all eight recruits for grant funding. The PIC's recommendations will be come to the February Oversight Committee meeting for approval.

If all recruitment awards are recommended by the PIC and approved by the Oversight Committee in this cycle, CPRIT will have awarded $67.7 million so far in FY 2016 for 18 recruitment awards. This is $700,000 more than was awarded for all recruitments in FY 2015. Historically, nearly 23% of recruits decline their offer.

16.2 and 17.1 Academic Research Applications in Peer Review

Applications for High Impact High Risk Grants (HIHR), Core Facilities Support Awards (CFSA), and Multi-Investigator Research Awards (MIRA), and 17.1 Core Facilities Support Awards for Competitive Renewals are currently being reviewed. We received 153 HIHR applications, 31, MIRA applications, 18 CFSA applications, and 6 CFSA – renewal applications

for a total of 208 applications. Two HIHR applications were administratively withdrawn from review for exceeding institutional limits. The remaining applications will be discussed at the March 9-16, 2016 peer review meetings in Dallas. Recommendations will come to the May 2016 Oversight Committee meeting for approval.

17.1 Research Request for Applications (RFAs) to be Released February 19

Research RFAs for Cycle 17.1 are currently being finalized and will be posted on February 19, 2016. These include Research Training Awards (RTA), untargeted Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancers in Childhood and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Individual Investigator Research Awards for Computational Biology (IIRACB), and Early Translational Research Awards (ETRA).

Information Session for Potential Applicants Interested in Computational Biology

Dr. Kripke and Michael Brown conducted an information session on January 19 at The University of Texas M.D. Anderson Cancer Center to discuss CPRIT's computational biology award program. I attended the meeting in Houston and introduced Dr. Jim Willson, CPRIT's new CSO, who was also attending the meeting. Oversight Committee member Dr. Bill Rice participated by telephone.

The session was held for potential applicants so that they can better understand CPRIT's computational biology award program and what CPRIT requires for a successful application. CPRIT plans to release its second RFA for computational biology awards in February. The session was hosted by M.D. Anderson and open to any institution within the state. Interested researchers were also able to participate via web streaming. The session was well attended; nearly 100 people attended the session in person and more attended by telephone or webinar. The webinar and presentation slides are now available under "Research Grant Webinars" on our website.

Advisory Committees

The University Advisory Committee (UAC) and Advisory Committee for Childhood Cancer (ACCC) are currently working on annual reports that will be presented at the February Oversight Committee meeting. You will receive copies of their reports in your meeting packets prior to the Oversight Committee meeting.

Product Development Research Program Update

Product Development Cycle 15.4 Award Contract Ready to be Executed

The Oversight Committee approved an award to Ruga Corporation with several contingencies. Ruga has been working to satisfy these requirements. Mike Lang, CPRIT's Chief Product Development Officer will present his recommendation at the February 17 meeting that Ruga has successfully addressed all pre-contract contingencies.

Product Development Review Cycle 16.1 Applications Undergoing Due Diligence

Five applicants were recommended for due diligence reviews following the Product Development Research program panel reviews held in December. The business/regulatory due diligence and intellectual property reviews are expected to be complete in March for Product Development Review Council (PDRC) review and consideration. The PDRC's recommendations will be submitted for PIC and Oversight Committee consideration in May. The total amount requested by the five applicants is $50,221,088.

Product Development Review Cycle 16.2 Applications Now Available

Requests for Texas Company and Company Relocation applications were posted to CPRIT's website in December. CPRIT's online portal is now open for application submission through February 28. The first review panel meetings will be held in early April to select the companies that will be invited for in-person presentations. Award recommendations from this cycle are expected to be considered by the Oversight Committee in August or September.

Product Development Review Council (PDRC) Membership

Dr. Kapil Dhingra, a PDRC member since 2010, is no longer able to participate with the PDRC due to other professional commitments. After discussion with the PDRC members, CPRIT has recruited two new PDRC members, Dr. Robert Sarisky and Dr. Neil Spector. Dr. Sarisky has a PhD and MBA and is currently Vice President of Business Development for Johnson & Johnson Pharmaceutical Services Oncology division. Dr. Neil Spector is an Associate Professor of Medicine at Duke University and the Co-Director of Experimental Therapeutics Program at the Duke Cancer Institute. Although they will be new to the PDRC, both Dr. Sarisky and Dr. Spector have been valuable members of the CPRIT Product Development Research review panels. Adding two members to the PDRC not only allows CPRIT to benefit from a wider scope of expertise but also increases the resources available to conduct progress and tranche reports.

Early Translational Research Awards (ETRA) – Business Plan Review

The Oversight Committee approved 20 ETRA grants to Texas academic institutions in November 2014. The objective of an ETRA grant is to "bridge the gap between promising new discoveries achieved in the research laboratory and commercial development." Consistent with that objective, one of the program requirements for these ETRA grantees is to submit business plans by March 31. The process of developing a business plan for the CPRIT project is intended to confirm that the principal investigator is taking appropriate steps toward developing a valid commercial opportunity for the CPRIT-funded technology. Product Development reviewers with business expertise will individually review the business plans and provide feedback to the ETRA grantees. The business plan requirement started with these ETRA grants and will be used again for the next round of ETRA grantees.

Company Connections and Other Activities

Since joining CPRIT late last year, Mr. Lang has met with 14 of CPRIT's active Product Development Research Program portfolio companies and several prospective applicant companies. He has also met with representatives of Johnson & Johnson's R&D incubator in Houston, The University of Texas MD Anderson Cancer Center, and the Texas Healthcare and Biosciences Institute (THBI), a Texas health sciences advocacy organization based in Austin. While getting a lay of the land in Texas, he is also identifying the best ways that the CPRIT's Product Development Research Program can support current and prospective portfolio companies and to enhance connections with the Texas bioscience community, including technology transfer offices at Texas institutions. Mr. Lang is also assessing investment strategies and policies to optimize CPRIT's economic development and clinical impact within the parameters of the Oversight Committee's established program priorities. He will briefly report on these projects at the February meeting. Mr. Lang plans to meet individually with all Oversight Committee members in the next few months.

Prevention Program Update

FY2016 Review Cycle 1 Award Contracts

Dr. Garcia and Ramona Magid scheduled calls with the 11 programs approved for awards by the Oversight Committee in November. These provided an overview of the project and budgets, a discussion of contract negotiation next steps, and an opportunity for questions and answers.

FY2016 Review Cycle 2 Applications Due in March

Six Requests for Applications were released on September 24, 2015. Applications are due March 3. Peer reviewers are being invited to participate on review panels that will meet May 23-25 in Dallas.

Other activities

A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's third party grant management contractor. Report specifications were provided to SRA and a first draft was produced. The draft will undergo several more iterations.

A visit to the Rio Grande Valley (RGV) is planned for Feb 3-5. It will include meetings with the dean of the new UTRGV Medical School as well various meetings with representatives of some of the local hospitals, Federally Qualified Health Clinics, a CPRIT grantee, and area legislators and legislative staff.

Communications Update

CPRIT 2015 Conference Report

Staff are finalizing the conference report and will present it to the Oversight Committee at the February meeting. Videotaped interviews conducted at the conference with various prevention, academic research and product development research grantees are being edited and will be shared on CPRIT's website when available. Speaker presentations have been posted on the conference website (www.CPRIT2015.org).

CPRIT Messages

- The Annual Report was published on January 21 and distributed to the legislature and the Oversight Committee per state law.
- The communications team is developing plans for the upcoming year to include an informational tour in April and preparation of materials for the upcoming legislative session.
- Staff have drafted a Request for Proposals for a contractor to assist with redesign of the website. A contract will be presented to the Oversight Committee for approval in May.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources. The number of CPRIT's Twitter followers has grown by 36 percent and CPRIT's Facebook page "likes" have increased by nearly 20 percent from 2014-2015.

Operations and Finance (Contracts, RFPs, Audit)

Requests for Proposal

CPRIT staff evaluated the six proposals from accounting firms received in response to the Request for Proposal for FY 2016 internal audit services. The internal audit services contract recommendation will be presented to the Oversight Committee at the February 17 meeting.

Staff Presentations/Meetings/Training

Kristen Doyle, Heidi McConnell, Dr. Kripke and I met on January 14 with representatives from the Gillson Longenbaugh Foundation concerning partnership opportunities. The Gillson Longenbaugh Foundation is based in Houston and provides funding for cancer research.

On January 14, Dr. Kripke gave a presentation to the Research Fellows of the Colleges of Pharmacy during the American Association of Colleges of Pharmacy annual meeting, which was held in Houston this year. She spoke on "CPRIT: A unique funding model for cancer research" and on leadership development.

Also on January 14 I met with an external affairs representative from the new Dell Medical School at The University of Texas at Austin. She updated me on opening status and preparation and I discussed CPRIT activities.

I provided an update on CPRIT activities to a gathering primarily consisting of University of Texas System component research and vice presidents on January 28, 2016.

Upcoming Oversight Committee-related Meetings

The next Oversight Committee will be held February 17, 2016, at 9:00 a.m. in the Capitol Extension. **Please note the new starting time for the meeting (9:00 a.m.)**, which was approved by the Oversight Committee at its meeting in November.

The dates and times for the upcoming February subcommittee meetings are listed below.

Board Governance –	February 4 at 10:00 am
Diversity –	February 5 at 10:30 am (cancelled)
Audit –	February 8 at 10:00 am
Prevention –	February 9 at 10:00 am
Scientific Research –	February 10 at 10:00 am
Product Development –	February 11 at 10:00 am
Nominations –	February 12 at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date. If you or your assistant did not receive a calendar invite from CPRIT staff for subcommittee meeting dates in February, please contact Mary Gerdes at mgerdes@cprit.state.tx.us.

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CPRIT has awarded **992** grants totaling **$1.471 billion**

- 158 prevention awards totaling $155.4 million
- 834 academic research and product development research awards totaling $1.316 billion

Of the $1.316 billion in academic research and product development awards:

- 31.4% of the funding ($412.6 million) supports clinical research projects
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- 15.8% of the funding ($208.4 million) supports discovery stage research projects
- 3.4% of funding ($44.4 million) supports training programs.

CPRIT has 11 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 2 Product Development Research
- 6 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: CPRIT ACTIVITIES UPDATE – DECEMBER 2015

DATE: JANUARY 6, 2016

Topics in this update include: CPRIT staffing, legislative and related briefings, the 2015 report on the Economic Assessment of Cancer, the Compliance and Program Updates, Operations (including contracts and audits), staff presentations and meetings, and upcoming subcommittee Meetings.

Personnel Changes and Job Openings

The Chief Scientific Officer (CSO) Interview Committee met in Austin on October 26 and 27 to interview five candidates and again on December 8 to interview a sixth candidate. An offer was made to one of the candidates in December following the interviews and discussion with the CSO Interview Committee. As I communicated to the Oversight Committee via email, the offer was accepted on December 23. The new CSO has requested that CPRIT not publicly announce his acceptance until later in January to give him time to personally inform his current patients and colleagues of his new position. Transition details are being finalized and the public announcement will be coordinated his current employer. We expect that the new CSO will begin work March 1, 2016.

An Administrative Assistant and a Grant Accountant position were reposted through January 22. In the interim, both are filled by temporary contract employees.

CPRIT currently has 32 authorized full-time equivalent (FTE) positions all of which are filled with either permanent or temporary contract personnel.

Legislative and Related Briefings

On December 8, 2015, several CPRIT senior staff members met with a member of Rep. Sarah Davis' staff to provide an update on CPRIT's activities. Rep. Davis has closely followed CPRIT-related issues in past legislative sessions.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | www.cprit.state.tx.us

On January 5, 2016, Heidi McConnell, Kristen Doyle, Becky Garcia and I met with CPRIT's budget analyst from the Governor's Office to discuss performance measures to be used in making CPRIT's request for legislative appropriations for the 2018-19 fiscal biennium.

Economic Assessment of Cost of Cancer in Texas in 2015

The Perryman Group conducts an annual economic assessment of the cost of cancer in Texas for CPRIT and recently issued its report, *An Economic Assessment of the Cost of Cancer in Texas and the Benefits of the Cancer Prevention and Research Institute of Texas (CPRIT) and Its Programs: 2015 Update*. CPRIT is statutorily required to provide an annual estimate of how much cancer has cost the state, including the amounts relating to cancer spent by the state child health program, the Medicaid Program, the Teacher Retirement System of Texas and the Employees Retirement System of Texas. The information is included in CPRIT's annual report.

The Perryman Group report on CPRIT finds the cost of cancer in Texas is about $31.3 billion in 2015, which is $1.1 billion lower than in 2014. Total losses attributable to cancer in Texas in 2015, including spinoff effects, is estimated to be $77.3 billion in output and over 818,000 jobs. The report also assessed the current total annual impact of all CPRIT operations, finding that $762.4 million in outputs (real gross product) and 11,342 jobs can be attributed to CPRIT. According to the report, "The most recent cancer statistics indicate that incidence and outcomes in Texas are improving relative to those in the nation as a whole, due in part to CPRIT efforts."

Compliance Program Update

Submission Status of Required Grantee Reports

A summary of delinquent/missing reports is produced by CPRIT's grant management system (CGMS) every week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities and receives approximately 550 grantee reports each month.

As of the most recent CGMS report (December 23, 2015), 29 required grantee reports from 14 entities have not been filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to expeditiously resolve filing issues.

Financial Status Reports (FSRs) Reviews

CPRIT's grant compliance specialists have performed 229 second level reviews of grantee FSRs during December. A total of 874 second level reviews have been performed during FY 2016. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Seventeen desk reviews were performed during December, bringing the FY 2016 year-to-date total to 101 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit or have an audit performed according to Agreed Upon Procedures. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after close of the grantee's fiscal year. Grant compliance specialists are currently working with 13 grantees towards resolution of outstanding audit findings.

Training and Technical Assistance

Pursuant to the newly adopted rule (T.A.C. § 703.22) establishing mandatory compliance training requirements, the Compliance Program is developing a comprehensive training curriculum for new and current grantees. These training programs are expected to include a combination of on-site training and web-based training covering administrative rule requirements, reporting requirements, CGMS overview, and Compliance Program overview. compliance staff will begin conducting trainings for new and current grantees beginning January 2016.

Reminder – Oversight Committee Member Political Contributions Form Due January 31

Health & Safety Code § 102.101(f) requires each Oversight Committee member to report political contributions over $1,000 to a candidate for a state or federal office made in the five years preceding the member's appointment to CPRIT and each year after the appointment until the member's term expires. This information should be submitted to the Chief Compliance Officer by January 31st of each year.

Mr. Burgess emailed the PDF form for Oversight Committee members to complete, sign, and return to his attention by January 31, 2016. Please include all political contributions over $1,000 to candidates for state or federal office for calendar year 2015. If you have no contributions to report, please note that on the form that you return to CPRIT. Please contact Mr. Burgess if you have any questions.

Scientific Research Program Update

Research Cycle 16.2 and 17.1

Applications submitted in response to the Requests for Applications (RFAs) for High Impact High Risk Grants, Core Facilities Support Awards, and Multi-Investigator Research Awards, and the Cycle 17.1 Core Facilities Support Awards for Competitive Renewals are currently being reviewed by peer review panels. The peer review panels will meet March 9-16, 2016, to discuss these applications. Applications recommended for grant awards will come to the Oversight Committee for approval in May.

Research Cycle 17.1 Research Request for Applications

We are currently working on six RFAs to be released in late February. These include the targeted and non-targeted Individual Investigator Research Awards (IIRAs), a Research Training Award RFA for unsuccessful applicants from the previous round, and Early Translational Research Awards.

Because of the low success rate for the IIRA Computational Biology applicants in the last round, Research Program staff will conduct an informational session for applicants at M.D. Anderson on January 19, 2016. Feedback on the reviewers' comments will be presented in an attempt to improve the success of resubmitted applications, and feedback from applicants regarding the process will be solicited. This will be an in person and online session.

Research Cycle 16.5 and 16.6 Recruitment Applications

The Scientific Review Council will meet on January 14, 2016, to discuss eight recruitment applications that were submitted in November and December. There were three Recruitment of Established Investigators, one Recruitment of Rising Stars (RRS), and four Recruitment of First-Time Tenure-Track Faculty applications submitted. Recommended applications will be presented at the February Oversight Committee meeting for approval.

Other Activities

The University Advisory Committee (UAC) and Advisory Committee for Childhood Cancer (ACCC) are currently working on annual reports that will be presented at the February Oversight Committee meeting.

Product Development Program Update

New Chief Product Development Officer Mike Lang has started meeting with Oversight Committee members to discuss their programmatic interests and goals. In addition, he has had introductory meetings with industry representatives and site visits with several current CPRIT product development companies. As Mike familiarizes himself with Oversight Committee priorities and addresses various company specific issues with CPRIT portfolio companies, he is working on several projects, including:

- Developing a process to evaluate business plans submitted by Early Translational Research Awards (ETRA) grantees;
- Evaluating the Texas cancer research and product development landscape to identify areas to leverage CPRIT involvement; and
- Assessing investment strategies and policies to optimize CPRIT's economic development and clinical impact within the parameters of the Oversight Committee's established program priorities.

Product Development Cycle 15.4

On November 19 the Oversight Committee approved an award to Ruga with several contingencies. Staff is working with Ruga to address these requirements.

Product Development Cycle 16.1

Two Product Development review panels met December 1-3, 2015, for in-person presentations by 12 applicant companies. Five companies were recommended for additional due diligence including four start-up drug development companies and a radiation therapy company. Business

and regulatory due diligence and intellectual property review are expected to be completed by March. The Product Development Review Council will meet to consider the due diligence reports and make award recommendations to the PIC and Oversight Committee for approval in May.

Product Development Cycle 16.2

Two requests for Applications were released December 28, 2015. CPRIT will accept submissions January 14 - February 28, 2016. Applications submitted for Cycle 16.2 are expected to be considered no earlier than the August 17, 2016, Oversight Committee meeting.

Prevention Program Update

FY2016 Review Cycle 1

Dr. Garcia and Ramona Magid scheduled calls with the 11 programs approved for awards by the Oversight Committee on November 19. These provided an overview of the project and budgets, a discussion of contract negotiation next steps, and an opportunity for questions and answers.

FY2016 Review Cycle 2

Six Requests for Applications were released on September 24, 2015. Applications are due March 3, 2016. Peer reviewers are being invited to participate on review panels that will meet May 23-25 in Dallas.

Other activities

A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's third party grant management contractor. Report specifications were provided to SRA and a first draft was produced. The draft will undergo several more iterations.

Quarterly progress reports were submitted and reviewed.

Communications Update

CPRIT 2015 Conference

Staff are waiting for remaining invoices to finalize the conference report that will include attendance statistics, registrant survey results and final budget information. Videotaped interviews conducted at the conference with various prevention, academic research and product development research grantees are being edited and will be shared on CPRIT's

website when available. Speaker presentations have been posted on the conference website (www.CPRIT2015.org).

CPRIT Messages

- A new Achievements Report was made available on December 4.
- The Annual Report is in final draft stages and is on schedule to be published by the January 31 deadline.
- The communications team is developing plans for the upcoming year to include an informational tour in late February or March and preparation of materials for the upcoming legislative session.
- Staff are drafting a Request for Proposals for a contractor to assist with redesign of the website.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources. The number of CPRIT's Twitter followers has grown by 36 percent and CPRIT's Facebook page "likes" have increased by nearly 20 percent from 2014-2015.

Operations and Finance (Contracts, RFPs, Audit)

Audits

McConnell & Jones LLP completed the financial audit of CPRIT for the year ending August 31, 2015, (FY 2015) and presented their report to the Audit Subcommittee on December 11, 2015. In McConnell & Jones' opinion CPRIT's financial statements present fairly the activities and fund information of the agency. The report closes the compliance findings reported in FY 2014 and reports a new finding related to CPRIT's not posting a Request for Application (RFA) in the *Texas Register* and the incorrect information being included in the grant pedigrees related to that RFA. CPRIT staff have already addressed this issue.

A bound copy of this audit was mailed to Oversight Committee members at the end of December. It was included in a packet with a bound collection of the FY 2015 internal audit reports and *Internal Audit Annual Report for FY 2015*, as well as a bound copy of the agency's *Annual Financial Report for the Year Ended August 31, 2015*. If you did not receive this packet, please let me know

Requests for Proposal

On November 29, 2015, CPRIT issued a Request for Proposal for internal audit services for FY 2016. CPRIT received six proposals from accounting firms by the closing date, December 29, 2015. Those proposals are being evaluated by staff and a recommendation for an audit firm will be presented to the Oversight Committee at the meeting in February.

Staff Presentations/Meetings/Training

Kristen Doyle spoke at the 2015 Texas Life Science CEO Summit on December 3, 2015, about CPRIT's product development program.

Dr. Kripke will give a presentation about CPRIT's grant programs to the Academic Research Fellows of the American Association of Colleges of Pharmacy in Houston on January 14.

Upcoming Oversight Committee-related Meetings

The next Oversight Committee will be held February 17, 2016, at 9:00 a.m. in the Capitol Extension. **Please note the new starting time for the meeting (9:00 a.m.)**, which was approved by the Oversight Committee at its meeting in November.

The dates and times for the upcoming February subcommittee meetings are listed below.

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- 2 Product Development Research
- 6 Prevention

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	5		77										82	
New Grant Contracts Signed	8	0	1	4	22								35	
New Grant Contracts In Negotiation			43										43	
Grant Reimbursements Processed	31	7	266	208	529								1,041	
Grant Reimbursements Processed	$ 2,897,094	$ 23,414,469	$ 19,906,130	$ 21,102,375	$ 41,408,221								$ 108,728,289	
Revenue Sharing Payments	$ -	$ 10,117	$ 4,959	$ -	$ 21,122								$ 36,198	$ 2,249,715
Total Value of Grants Contracted	$ 49,662,860	$ -	$2,000,000	$ 9,202,957	$ 34,629,354								$ 95,495,171	
Grants Awarded (#)/ Applications Rec'd (#)	12%	11%	13%	13%	13%									
Debt Issued ($)/Funding Awarded	62%	62%	58%	58%	62%									
Grantee Compliance Trainings/Monitoring Visits	3	2	2	0	3								10	
Awards with Delinquent Reimbursement Submission (FSR)			5											
Awards with Delinquent Matching Funds Verification			10											
Awards with Delinquent Progress Report Submission			4											
IA Agency Operational Recommendations Implemented	0	6	6	6	6									
IA Agency Operational Recommendations In Progress	13	7	7	7	7									
Open RFAs	17	14	9	9	11									
Prevention Applications Received	0	0	0	0	0								0	505
Product Development Applications Received	25	0	0	0	0								25	277
Research Applications Received	4	212	2	6	5								229	4,012
Help Desk Calls/Emails	193	289	231	159	143								1,015	
MISSION														
RESEARCH PROGRAM														
Number of Research Grants Awarded (Annual)			55										55	
Recruited Scientists Announced														131
Recruited Scientists Accepted														104
Recruited Scientists Contracted														89
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Open Clinical Trials (#)														53
Number of Patents Resulting from Research														
Number of Patent Applications														

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development Grant Awarded (Annual)			1										1	
Life Science Companies Recruited (in TX)														7
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														
Open Clinical Trials (#)														7
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			12										12	
People Served by CPRIT-Funded Prevention and Control Activities			120,112										120,112	
People Served through CPRIT-Funded Education and Training			58,126										58,126	
People Served through CPRIT-Funded Clinical Services			61,986										61,986	
TRANSPARENCY														
Total Website Hits (Sessions)	8,560	7,901	8,581	4,617	5,993								35,652	
Total Unique Visitors to Website (Users)	5,778	5,472	5,679	3,376	4,435								24,740	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: UPDATE OF RESEARCH ACTIVITIES

DATE: FEBRUARY 17, 2016

Research Grants Currently Under Review

Applications for High Impact High Risk Grants (HIHR), Core Facilities Support Awards (CFSA), and Multi-Investigator Research Awards (MIRA), and Core Facilities Support Awards for Competitive Renewals are currently being reviewed. We received 153 HIHR, 31, MIRA, 18 CFSA, and 6 CFSA – renewal applications for a total of 208 applications. Two HIHR applications were withdrawn for exceeding institutional limits. Applications will be discussed at the March 9-16, 2016 peer review meetings in Dallas. Successful applications will come to the May 2016 OC meeting for approval. Please contact Michael Brown if you would like to arrange to attend any of the peer review meetings.

New Requests for Applications

Research RFAs are currently being finalized and will be posted on February 19, 2016. These include Research Training Awards, untargeted Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancers in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Individual Investigator Research Awards for Computational Biology (IIRACB), and Early Translational Research Awards (ETRA). These applications will be due May 19, 2016, reviewed from June to September 2016, and come to the November 2016 OC meeting for approval.

Recruitment Applications

Twelve applications were submitted in response to Recruitment of Established Investigator (REI), First-Time, Tenure Track Faculty Members (RFT), and Rising Stars (RRS) Request for Applications in cycles 16.4, 16.5, and 16.6. No applications were administratively rejected for ineligibility. Eight applications were recommended for funding by the SRC for all 3 cycles. Four Established Investigators, three First-Time, Tenure-Track Faculty Members, and one Rising Star were recommended by the SRC and PIC for a total of $34,000,000. Subsequent to the PIC meeting, one RFT applicant declined, making a total of $32M to be acted upon at this meeting.

In the next cycle, five applications (2 REI and 3 RFT) were received, and all applications were reviewed. No applications were administratively rejected for ineligibility. The SRC met to discuss the five applications on Thursday, February 11, 2016. Recommended applications will come to the May, 2016, OC meeting for approval.

Computational Biology RFA Information Session

Staff conducted an information session on Tuesday, January 19th at The University of Texas M.D. Anderson Cancer Center to discuss the IIRACB program. This session was being conducted in response to a request from the institutions and PIs so that they could better understand the IIRACB program and what CPRIT requires in a successful application. The session was open to any institution within the state that wanted to participate via web streaming.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	PREVENTION PROGRAM UPDATE
DATE:	FEBRUARY 2, 2016

The following report provides an overview of the Prevention Program activities from November 2015 through January 2016.

FY2016 Review Cycle 1

Dr. Garcia and Ramona Magid scheduled calls with the 11 programs approved for awards by the Oversight Committee on November 19. These provided an overview of the project and budgets, a discussion of contract negotiation next steps, and an opportunity for questions and answers.

FY2016 Review Cycle 2

Six Requests for Applications were released on September 24, 2015. Applications are due March 3, 2016. Peer reviewers are being invited to participate on review panels that will meet May 23-25 in Dallas.

Other activities

A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's third party grants management contractor. Report specifications were provided to SRA and 3 drafts have been produced. The draft will undergo several more iterations.

A visit to the Rio Grande Valley (RGV) is planned for Feb 3-5. It will include meetings with the Dean of the new UTRGV Medical School as well various meetings with representatives of some of the local hospitals, Federally Qualified Health Clinics and a CPRIT grantee.

Prevention Program Outcomes Data

Attachment 1 - Highlights of the prevention program outcomes data.

Attachment 2 - System change examples.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Attachment 1

CPRIT Prevention Program

as of February 2016

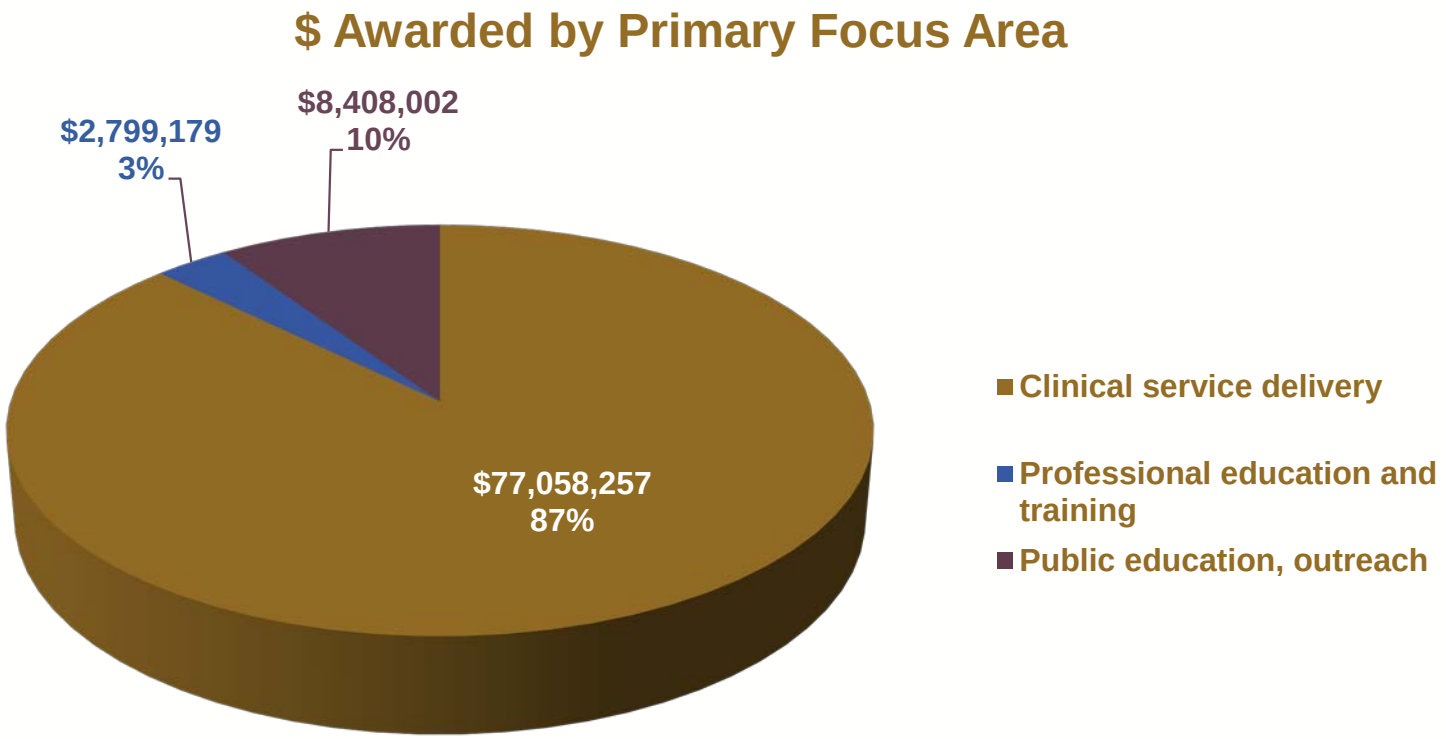
Total # Prevention Grants Awarded (As of February 2016)

	Number	Total $
Legacy Grants	13	$ 3,644,491
CPRIT Grants	145	$151,793,171
TOTAL	158	$155,437,662

Active Prevention Grant Awards (as of February 2016)

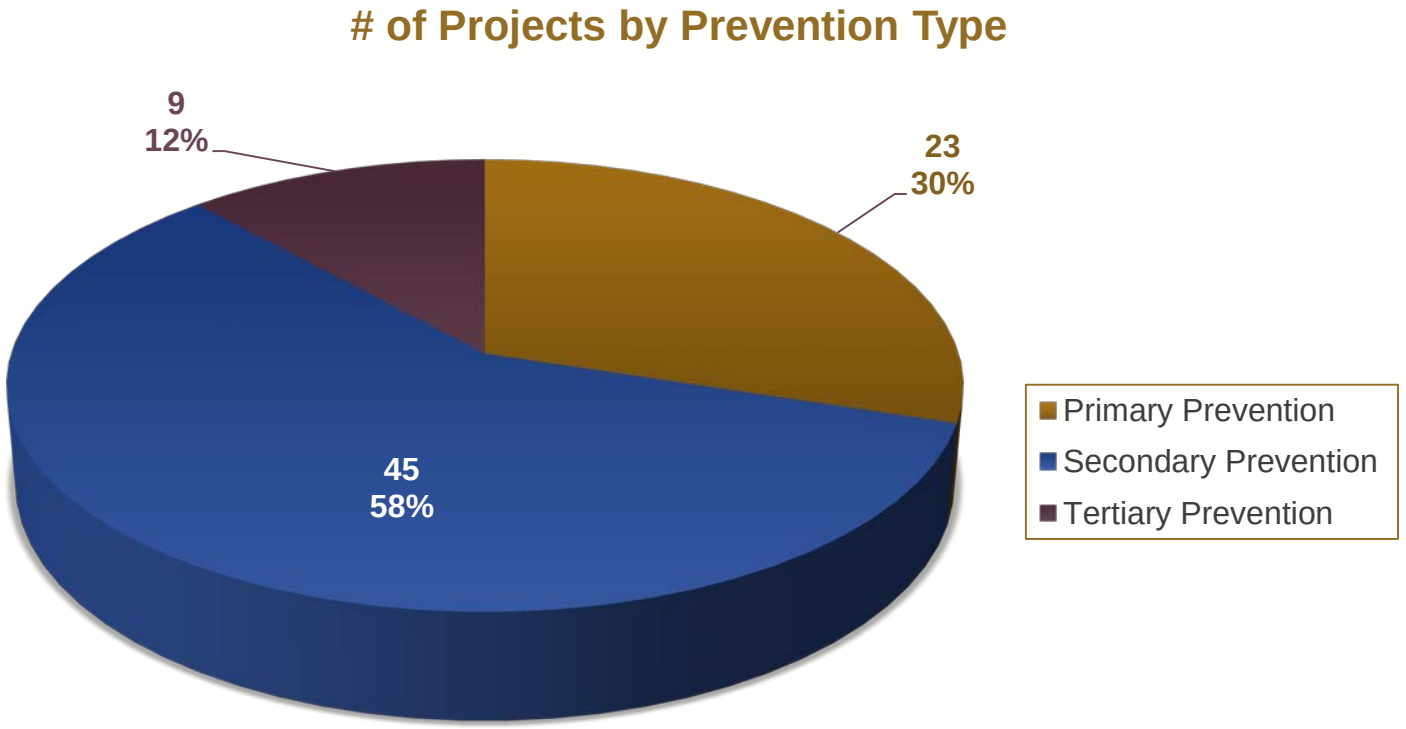
Mechanism	Number	Total $
Evidence-based Cancer Prevention Services	36	$59,871,634
Continuation/Expansion Projects	20	$25,564,530
Cancer Prevention Promotion and Navigation to Clinical Services	2	$779,691
Health Behavior Change Through Public and Professional Education and Training	4	$ 1,449,805
Dissemination Projects	2	$599,778
TOTAL	**64**	**$88,265,438**

Primary Focus Area
64 Active Prevention Grants



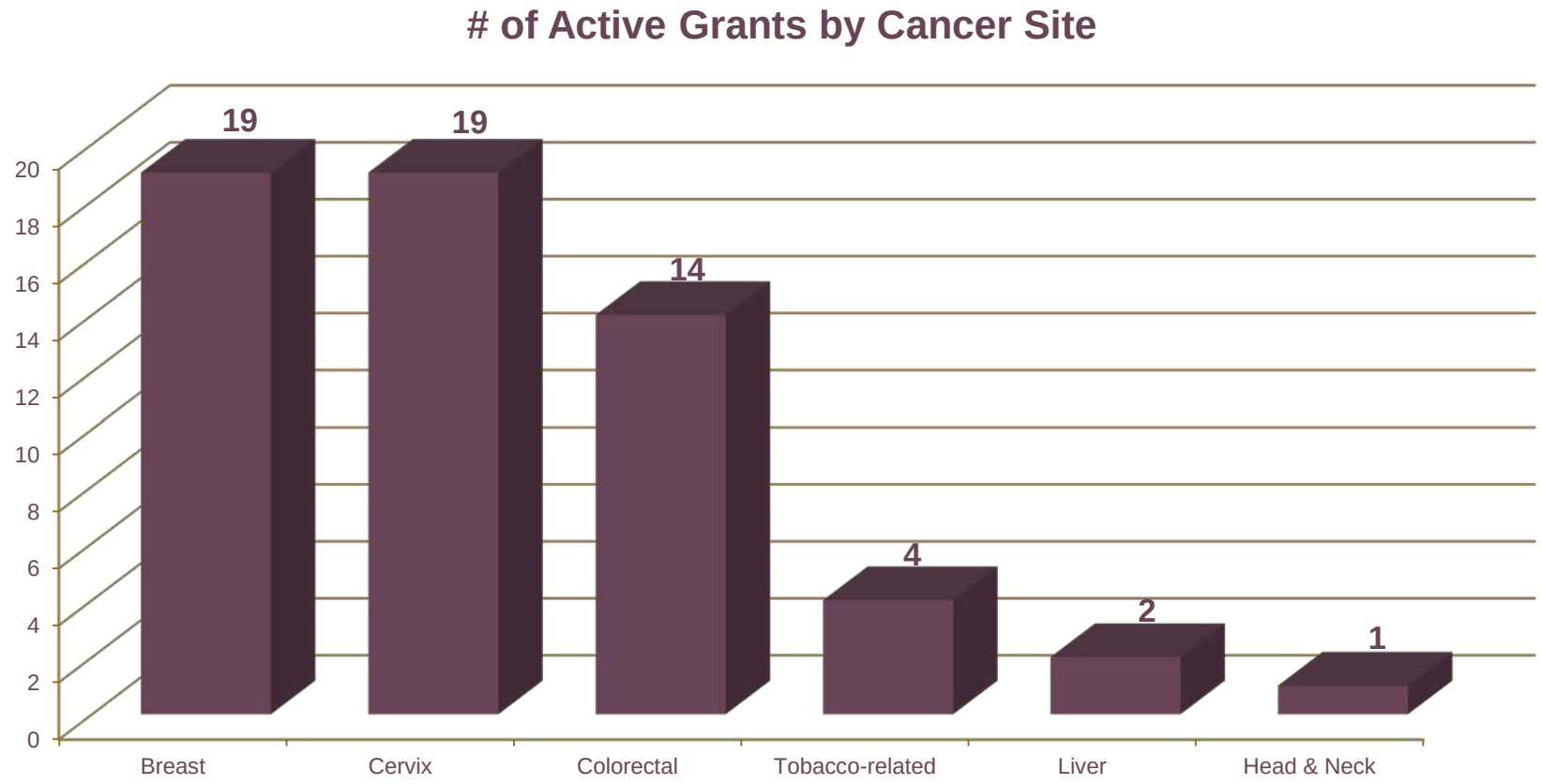
FEBRUARY 2016

Prevention Type
64 Active Prevention Grants

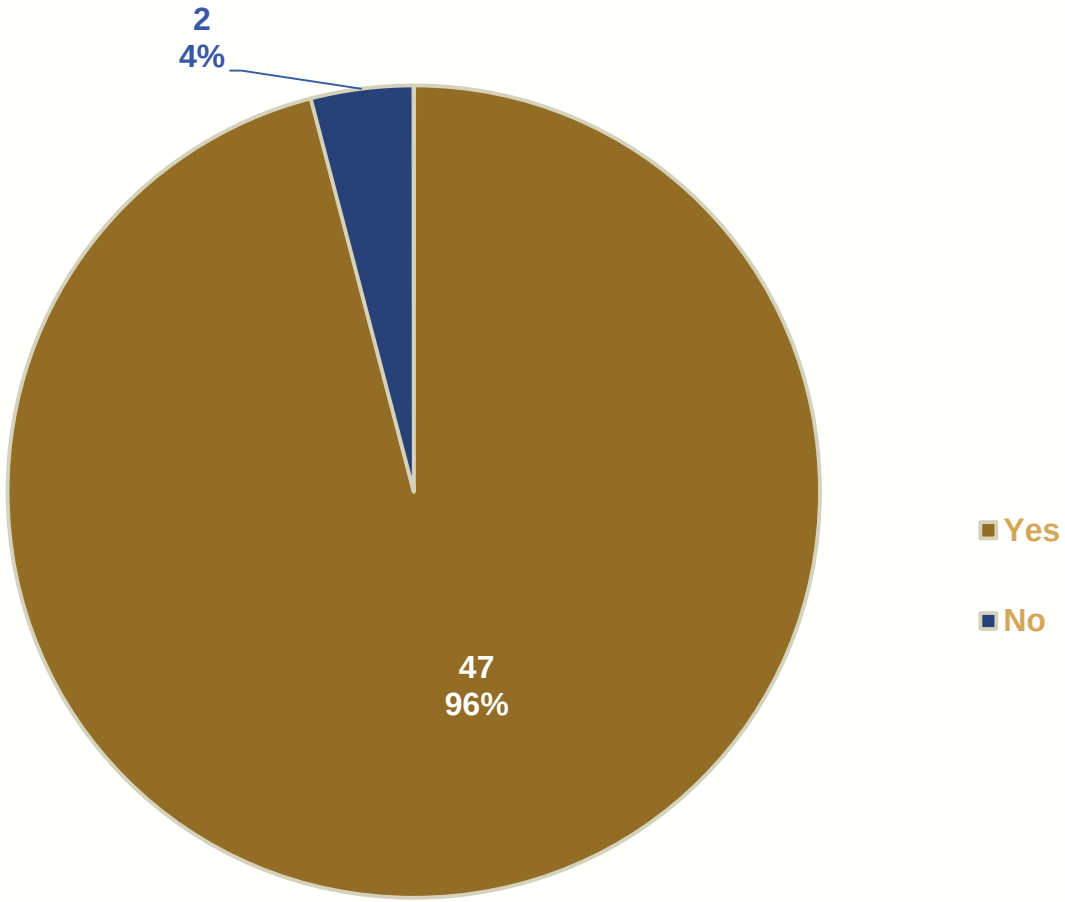


FEBRUARY 2016

Cancer Site
64 Active Prevention Grants

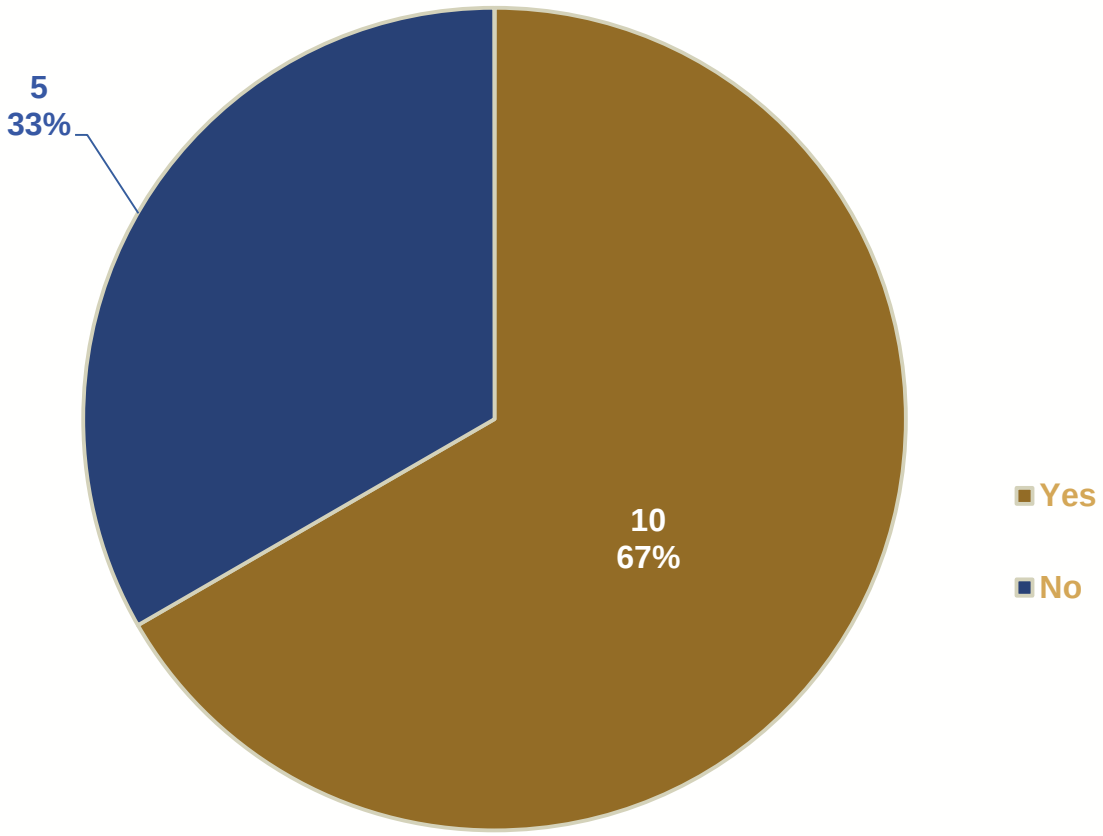


Academic Institutions collaborating with Non-academic Organizations (49/64 grants)



FEBRUARY 2016

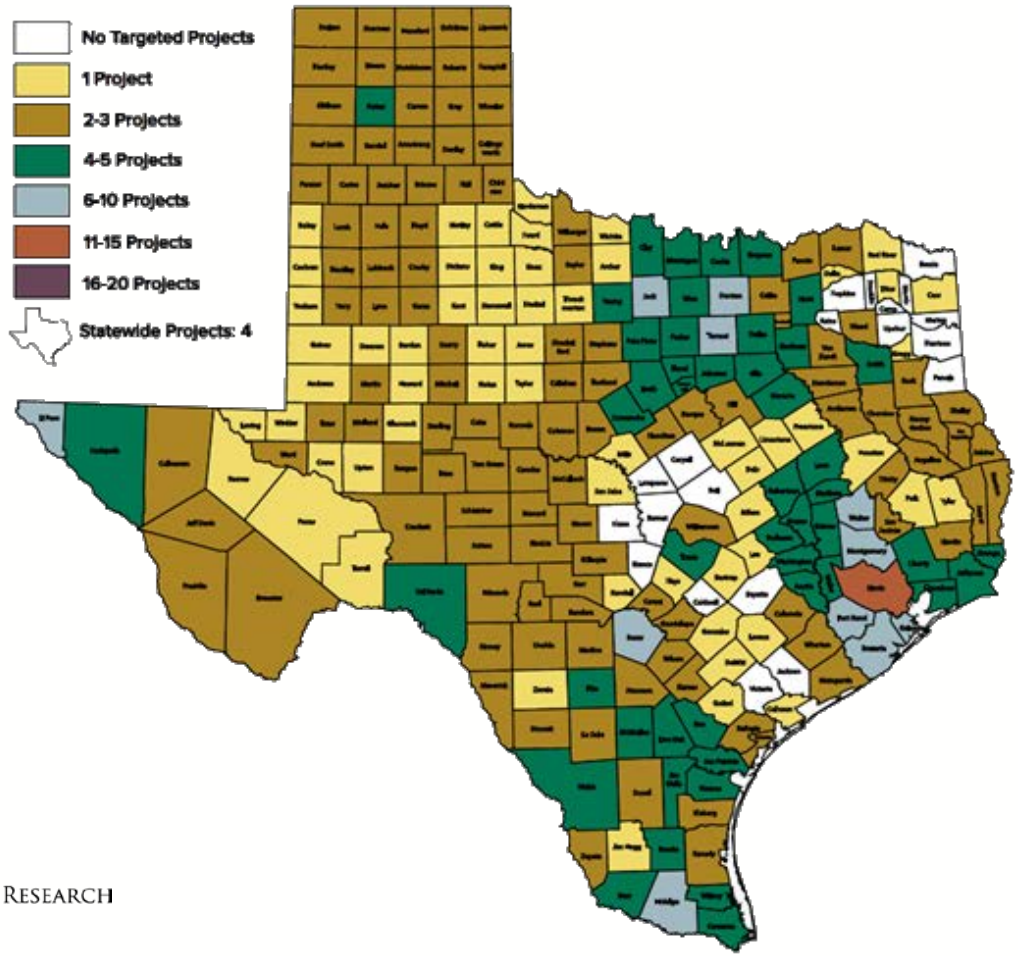
Non-academic Organizations collaborating with Academic Institutions (15/64 grants)



11/19/15

Geographic Coverage

Counties Served by CPRIT Prevention Projects
64 Active Projects – February 2016



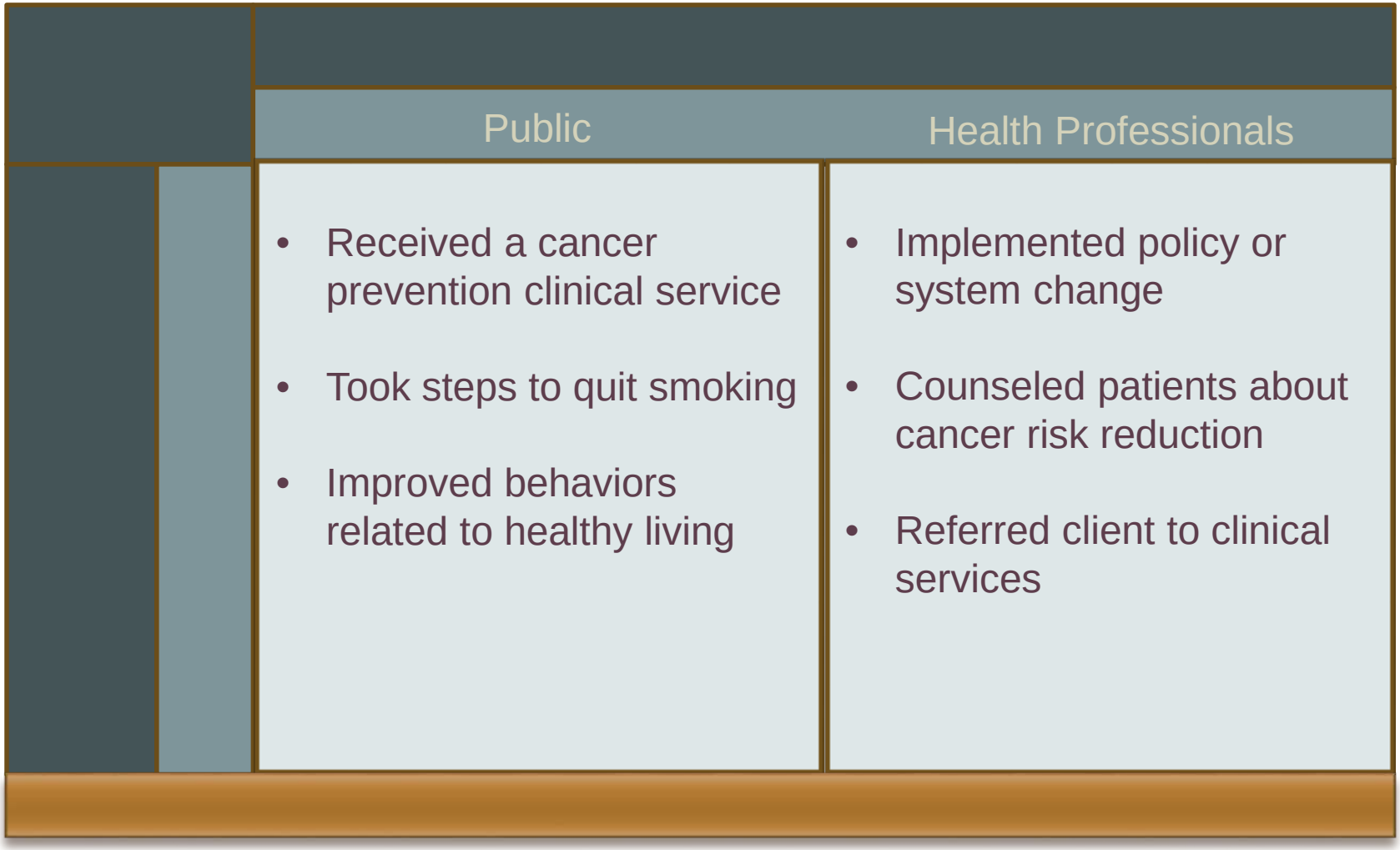
Over 2,749,225 Prevention Services for Texans

Grantee Reports Through November 2015

Education and Training	Clinical Service Delivery
1,269, 382	1,479,843

Actions Taken as a Result of Education/Training

Grantee Reports Through November 2015



Clinical Service Delivery

Grantee Reports Through November 2015

Screening Outcomes

Grantee Reports Through November 2015

239,282
people never before screened

671,012
breast, cervical, colorectal, and liver cancer screenings/diagnostics

1,955
cancers detected

4,192
Precursors detected

ATTACHMENT 2 – Examples of System Change and Improvement

Systems Change

In addition to the impact on the health of people in Texas, the Prevention grants are also having an impact on improving the healthcare system and fostering greater collaborations. Health system improvements include reducing wait times for diagnostic testing, reducing the number of people lost to follow-up, implementing patient reminder systems, enhancing electronic medical records and training a cadre of community health care workers to help educate and navigate people through the system. These grants have also stimulated greater collaboration among professional colleagues, academic institutions, community organizations and clinics.

Below are excerpts from reports of two grantees that illustrate the kinds of system change and improvements stimulated by CPRIT grants.

PP120091 – Developing a Comprehensive Cervical Cancer Screening for High Risk Uninsured and Underinsured Women in Harris County

Dr. Matthew Anderson, Baylor College of Medicine

This support has enabled us to spark a transformation of how cervical cancer screening services are delivered throughout Harris Health System [HHS], the 3rd largest safety net health system in the U.S. Perhaps most importantly, our review of the impact of this program on Harris Health System wide has shown remarkable results, decreasing the proportion of women non-compliant with screening from 17% to 11% and resulting in a dramatic shift of cervical cancer burden at Harris Health facilities to earlier, more treatable stages. Without question, this program has saved lives! Many of the changes PP120091 has precipitated, both in terms of culture and day to day operations will undoubtedly outlast the receipt of funding.

The second issue we have worked diligently to overcome has been creating culture change that has led to acceptance of a medical home for cervical cancer screening among medical professionals at each of the HHS CHCs [Community Health Centers] at which we operate. There have been many potential reasons for skepticism regarding our efforts. However, this has been overcome by establishing collaborative relationships; being available to assist with difficult cases, demonstrating our ability to streamline referrals for women needed additional services from gynecologists and/or gynecologic oncologists at other HHS facilities and our willingness to provide additional services that may not have been available at a particular CHC but which PCP (primary care providers) at that location felt were important.

Key Outcomes (Grantee summary):

- Dedicated medical homes have proven highly effective for improving low rates of cervical cancer screening and poorly performing HHS community clinics.
- Use of dedicated patient navigation system has reduced proportion of women with abnormal cervical cytology lost to follow up within HHS from ~40% to 0.3-0.5% over the past 9 months.

- Efforts by our program (in tandem with PP100201) have decreased the numbers of early stage cervical cancers diagnosed at HHS by 50%.
- Development of medical homes for providing colposcopy services appear to be popular and well-accepted both by patients and primary care providers alike.

PP110101--Eliminating Cancer Disparities in the Multicultural Community of Southwest Houston

Dr. Andrea Caracostis, Hope Clinic

- In 2011 HOPE Clinic proposed to increase cervical cancer screening and diagnosis through by referring abnormal Paps to Harris Health System. Within 3 months into the project the clinic realized that the wait time for a colposcopy at Harris Health was over 8 weeks and that the patients referred to private doctors could not afford the $350 cost. In addition any procedure if the diagnosis was positive represented additional hurdles to the patient. The [Hope] clinic decided to provide the diagnostic colposcopies in house and proposed to hire a Gynecologist who could correctly and efficiently handle low grade cervical cancer in house. With CPRIT funds the clinic purchased a colposcope ($1,500) and hired its first time part time obstetrician/gynecologist (Dr. Best). The clinic also received a donation of a loop electrosurgical excision procedure (LEEP) machine from a local church. By 2012 the clinic was providing colposcopies for a total expense of $50 including pathology and doing LEEPs on Atypical Squamous Cells of Undetermined Significance (ASCUS) patients. The time between abnormal Pap and diagnostic was reduced to 11 days! Since then HOPE has perfected its continuity of care, it currently employs 3 gynecologists. It obtained hospital privileges and is now able to address more complicated cervical cancer situations and provide surgical treatment when needed.

- HOPE Clinic has for many years worked to increase the mammogram screening rates within the Asian community and other underserved minorities. In partnership with The Rose it provided over 650 mammograms each year. Many of the mammograms that were abnormal were simple cysts that could be diagnosed in house on the day of the visit by ultra sound. With support from CPRIT once more, HOPE was able to purchase an ultra sound machine and would not only give peace of mind to women with small palpable masses but also save them the expense of additional diagnostic procedures. Today HOPE Clinic has 3 ultrasound machines and an ultrasound technician.

- The population that HOPE Clinic serves has a high incidence rate of hepatitis B, number one cause of liver cancer. HOPE Clinic received funds from CPRIT to increase early diagnosis. Throughout the years the clinic not only screened large number of people, but also developed cutting edge protocols that are currently being considered by the Centers for Disease Control for national implementation. The protocols include: screening for core-antigen in addition to the surface markers to identify dormant virus and prevent reactivation by drop in immunity and create awareness and education about this infection. The clinic also learned to screen for immunity markers before vaccinating adults and children not born in the US, this would not only allow the clinic to identify exposure, but

patients who have hepatitis B titers would not need to be vaccinated, saving the system the high cost of the vaccine. ($240 for 3 hepatitis B vaccines).

Key Outcomes (CPRIT summary):

- Reduced wait times and cost
- Reduced loss to follow up by providing diagnostic workup on the same day
- Increased availability of services
- Trained staff and improved the quality of the services through development of standard protocols

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	FEB. 17, 2016

The following report provides an overview of the agency's communications activities from November 19, 2015 through February 17, 2016.

EARNED MEDIA

The communications team worked with and pitched individual publications and reporters to secure positive coverage for CPRIT, including coordinating an interview with Xconomy and Dr. James Willson.

Additionally, the communications team distributed press releases announcing Michael Lang as Chief Product Development Officer and Dr. Willson as Chief Scientific Officer, resulting in several of the articles represented in the coverage highlights below.

Grant Awards Announcement: Following the Oversight Committee's approval, on Nov. 19, 2015, CPRIT distributed a press release to and pitched local, regional and national media announcing the awarding of 60 academic research grants, 12 prevention grants and one product development research grant which resulted in some of the coverage represented below.

Coverage: (Nov. 7, 2015 – Feb. 5, 2016)

- 12 articles featured CPRIT
- 71 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- Nov. 14, 2015, *Austin American-Statesman*, CPRIT Grant Helps Bring Cancer Researcher to UT, Dell Medical School
- Nov. 18, 2015, *BioNews Texas*, CPRIT Innovations IV Brings Leaders in Cancer Research to Austin
- Nov. 19, 2015, *San Antonio Business Journal*, San Antonio Lands Millions More in New Cancer Research Money
- Nov. 20, 2015, *Xconomy*, Michael Lang to Head Product Development for Texas Cancer Agency

- Nov. 20, 2015, *Houston Business Journal*, Major CPRIT Grant Brings San Francisco Pharma Company to Houston
- Nov. 24, 2015, *D Healthcare Daily*, CPRIT Awards UT Southwestern With $19.6 Million in Grant Money
- Jan. 22, 2016, *Austin Business Journal*, James Willson | Chief Scientific Officer | Cancer Prevention and Research Institute of Texas
- Jan. 22, 2016, *The Cancer Letter*, Willson Named CPRIT Chief Scientific Officer
- Jan. 29, 2016, *Xconomy*, Texas Cancer Agency Names James Willson Top Science Officer

CPRIT 2015 Conference

Staff has finalized an Innovations conference report (attached) that includes attendance statistics, registrant survey results and budget for the conference. Videotaped interviews conducted at the conference with various prevention, academic research and product development research grantees are being edited and will be shared on CPRIT's website when available. Speaker presentations have been posted on the conference website (www.CPRIT2015.org).

CPRIT Messages

- A new Achievements Report was made available on December 4, 2015.
- The Annual Report was published by the January 31 deadline.
- The Communications team is developing plans for a media tour in April and also preparing materials for the upcoming legislative session.
- Staff completed and submitted an RFP for a contractor to assist with redesign of the website.

Social Media

The communications team continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources. The number of CPRIT's Twitter followers has grown by 36 percent and CPRIT's Facebook page "likes" have increased by nearly 20 percent over the last year.

Austin American-Statesman

CPRIT grant helps bring cancer researcher to UT, Dell Medical School

By Dan Zehr Thursday, Nov. 12, 2015

The University of Texas at Austin on Thursday announced it has recruited a top cancer researcher from Vanderbilt University, luring him to a joint position in its engineering and medical schools with a $6 million grant from the Cancer Prevention and Research Institute of Texas.

Thomas Yankeelov, who develops advanced imaging methods to better identify, characterize and model tumors and their growth, will join the faculties of UT's Cockrell School of Engineering and Dell Medical School at the start of next year, the departments said in a joint press release.

UT's biomedical engineering department initially targeted Yankeelov, said Sharon Wood, dean of the engineering school. When university officials brought him in from the Vanderbilt-Ingram Cancer Center for an interview, they realized that his research could extend across a range of departments and schools.

He will be the first person to hold a joint, tenured position with the medical school, Wood said.

"He kind of fell into our lap," she said.

For his part, Yankeelov said the breadth of programs and resources at UT — along with the opportunity to get in on the ground floor of a new medical school — drew him to Austin.

"Our research program is sort of at the interface of mathematics, physics, engineering, modeling and cancer biology," he said. "Very few places in the country have opportunities in all those areas."

At its core, Yankeelov's research has led to imaging methods to more accurately understand tumors in humans. He can then use that data to produce models for how a tumor might grow and respond to various treatment options. Ultimately, those models could help doctors customize cancer therapies on a patient-specific basis.

"One of the things we've been very interested in doing is trying to tie computational medicine to clinical medicine," Wood said. "This represents a tremendous opportunity for us because he's doing both."

Wood suggested a scenario in which Yankeelov's imaging and modeling programs could help measure the reaction of a tumor in something closer to real time, rather than waiting until after a full course of chemotherapy to assess how well the treatment worked.

Clay Johnston, dean of the Dell Medical School, said that Yankeelov and his research can help "redefine what better cancer care means."

"A big reason the Dell Medical School exists is that Travis County voters wanted better cancer care closer to home," Johnston said in a news release.

Yankeelov said he will split the $6 million grant from the Cancer Prevention and Research Institute of Texas, or CPRIT, into the three primary tracks in his research — imaging, modeling and clinical treatment. About two-thirds will go to fund his research team and the rest for lab equipment and other needs.

The grant from CPRIT's "recruitment of established investigators" initiative is the first such award to any UT-Austin school, according to records posted on the institute's website. It's also the first CPRIT grant of any type directly awarded to a researcher or program at the Dell Medical School.

The state-backed CPRIT programs have become a powerhouse for drawing cancer experts to Texas universities. Its grants have helped land about 100 academic researchers with roughly $300 million in grants to date, according to records posted on its website.

http://www.mystatesman.com/news/business/cprit-grant-helps-bring-top-cancer-researcher-to-d/npLs5/

CPRIT Innovations IV Brings Leaders in Cancer Research to Austin

NOVEMBER 13TH, 2015 CHARLES MOORE

The fourth annual Cancer Prevention and Research Institute of Texas (CPRIT) hosted more than 800 researchers, scientists, physicians, cancer experts, company representatives and entrepreneurs engaged in the fight against cancer. Over a two-day packed conference agenda, keynote speakers and panelists presented and discussed key advances in academic research, cancer prevention, and product development, frequently challenging attendees with specific calls to action. The event, organized by the Innovations in Cancer Prevention and Research Conference, was held Nov. 9-10 at the Renaissance Arboretum Hotel in Austin, Texas.

In the "Promise and Perils of Immunotherapy" keynote session, world-renowned experts Jim Allison, PhD and Cassian Yee, MD, with The University of Texas MD Anderson Cancer Center and Malcolm Brenner, MD, PhD of Baylor College of Medicine (BCM), discussed the importance of immunotherapy as an effective addition to traditional forms of cancer treatment. The presenters highlighted the fact that four drugs have been approved to treat melanoma in 2015 alone.

Dr. Allison serves as the chair of the MD Anderson Immunology Department and is executive director of the Moon Shots Program Immunotherapy Platform. This year, he was named winner of the Lasker-DeBakey Clinical Medical Research Award, one of the world's most prestigious scientific awards, and also received the Science of Oncology Award by ASCO and the Pezcoller Foundation AACR International Award for Cancer Research. A CPRIT grant helped bring Dr. Allison back to his native Texas in 2012.

Dr. Yee is a professor in the Department of Melanoma Medical Oncology and Department of Immunology at MD Anderson, and also serves as the director of the Solid Tumor Cell Therapy program there. He is also a Burroughs Wellcome Scientist in Translational Research, an elected member of the American Society for Clinical Investigation, and co-leader of the Stand Up to Cancer Immunology Dream Team. CPRIT funding also helped bring Dr. Yee to Texas from the Fred Hutchinson Cancer Research Center at the University of Washington.

Dr. Brenner is founding director of the Center for Cell and Gene Therapy at BCM, Texas Children's Hospital, and The Methodist Hospital, and is currently a professor in the Departments of Pediatrics and of Medicine at BCM. He is also editor-in-chief of Molecular Therapy, and a former president of the American Society for Gene and Cell Therapy (ASGCT) and the International Society for Cell Therapy.

In the session, "The Evolution of Precision Oncology Biological Complexity, Big Data and Big Price," Arizona State University's George Poste, PhD, reported that more than 580,000 cancer deaths occurred in the United States in 2014, a year which also recorded $3 billion in cancer medication costs but only 40 percent of patients who responded to treatment. In order to improve efficacy, Dr. Poste said that cancer research needs a predictive rule set to serve as a blueprint for the next generation of discovery, which must include the ability to share data to create an extended cognosphere for the cancer research community.

Dr. Poste is chief scientist, Complex Adaptive Systems Initiative, Regents professor and Del E. Webb Chair in Health Innovation at Arizona State University (ASU), and serves on the board of directors of Monsanto and Exelixis, and the scientific advisory board of Synthetic Genomics. He is a vice chairman of Caris Life Sciences, and chief scientist, Complex Adaptive Systems Initiative (CASI) at ASU. Prior to working at ASU, Dr. Poste served as chief science and technology officer and president, R&D, of SmithKline Beecham, and has published over 350 research papers and edited 14 books on pharmaceutical technologies and oncology. A fellow of the Royal Society, Dr. Poste was honored in 1999 by Queen Elizabeth II as a Commander of the British Empire for his contributions to international security. He is currently a member of the U.S. Institute of Medicine Board on Global Health, and has served on advisory committees for multiple U.S. government agencies in the areas of defense, national security and healthcare.

Five of the Innovations Conference sessions focused on CPRIT's product development research program. During CPRIT "Companies in Action — Early Stage Successes," representatives from Asuragen, Aeglea BioTherapeutics, Mirna Therapeutics and Bellicum Pharmaceuticals reported how CPRIT's translational research funding sustained their early stage of product development that was critical to transferring ideas from bench to bedside. The panel also praised CPRIT's intensive peer review process, crediting it with validating the companies' ideas and attracting follow-on funding from venture capitalists. The panel closed by emphasizing CPRIT's positive impact on the Texas life sciences industry.
Abby Sandler, PhD, of the President's Cancer Panel, explained that the human papillomavirus, or HPV, vaccination rate is 33.4 percent in the U.S., lagging far behind several other countries. Dr. Sandler emphasized that an 80 percent vaccination rate could prevent 53,000 future cervical cancers, and noted that limited understanding of the vaccine, lack of provider recommendation, safety concerns, and misinformation created by 'Doctor Google' all pose challenges to increasing the vaccination rate for a preventable cancer.

Dr. Sandler has worked at the National Cancer Institute (NCI) since 1999 and served as executive secretary of the President's Cancer Panel since January 2005. Since 2013, she also has served as special assistant to the director, NCI Center for Cancer Research, on the Rare Tumors Initiative. Her research background focuses on molecular tumor virology and gene therapy.

Texas Speaker of the House Joe Straus made a special appearance at the Innovations Conference to thank attendees for their career contributions in the fight against cancer. Speaker Straus also congratulated CPRIT staff for re-establishing momentum in the agency's mission, commenting: "CPRIT is back … CPRIT is stronger than ever. Please know that the members of the Texas House believe in what you are doing. We want to keep working with you. And we know you'll continue to succeed."

At the closing session, "CPRIT: A Look Forward," University of Texas Systems Vice Chancellor for Research and Innovation Patricia Hurn, PhD, emphasized the importance of synergizing CPRIT resources with universities and companies, and investing in data mining to bring statewide scale to cancer research. Dr. Hurn serves as the chief health research officer to the UT System and its six academic healthcenter campuses, and is also an active neuroscientist and serves as a research professor in neurobiology in The University of Texas at Austin's College of Natural Sciences. She directs a translational laboratory that studies the role of hormones in post-stroke immunology.

Other panelists discussed the continuing economic benefit of CPRIT's early detection and prevention services, the importance CPRIT funding plays in moving promising research into product commercialization, leveraging the Governors Excellence Fund with CPRIT investments, and expanding recruitment of world-class researchers.

Since its establishment in 2009, the Cancer Prevention and Research Institute of Texas has awarded $1.35 billion in grants to Texas researchers, institutions, and organizations through its academic research, prevention, and product development research programs. Programs made possible with CPRIT funding have reached all of the state's 254 counties, brought more than 80 distinguished researchers to Texas, advanced scientific and clinical knowledge, and provided more than $2.5 million worth of life-saving education, training, prevention, and early detection services to Texans.

http://bionews-tx.com/news/2015/11/13/cprit-innovations-iv-brings-leaders-cancer-research-austin/

SAN ANTONIO BUSINESS JOURNAL

San Antonio lands millions more in new cancer research money

W. Scott Bailey Nov 19, 2015

San Antonio researchers will have more resources for their battle against cancer. The Cancer Prevention and Research Institute of Texas (CPRIT) has awarded more than $7.7 million to the University of Texas Health Science Center at San Antonio.

The largest Health Science Center award is $2 million to help fund the recruitment of Zhijie Liu from the University of California at San Diego's Howard Hughes Medical Institute.

CPRIT has also awarded the Health Science Center $1.5 million for its Genetic Risk Assessment for Cancer In All South Texas, or GRACIAS Texas, program. The funds will support genetic counseling services offered through the Health Science Center's Regional Academic Health Center.

CPRIT's latest round of funding includes 73 new grants totaling approximately $112 million. The Austin-based agency, which was launched in 2009, was set up to funnel $3 billion to support research and prevention efforts across the state.

CPRIT is nearing the halfway point of its funding authority. To date, the agency has awarded 992 grants totaling roughly $1.47 billion. With the new grants, CPRIT has now funded the recruitment of more than 100 top cancer researchers to Texas.

http://www.bizjournals.com/sanantonio/news/2015/11/19/san-antonio-lands-million-more-in-new-cancer.html

Michael Lang to Head Product Development for Texas Cancer Agency

Angela Shah November 19th, 2015

Xconomy Texas — The Cancer Prevention and Research Institute of Texas has hired a former biotech executive as its new chief product development officer. Michael Lang formerly had leadership positions NanoVision, a Pennsylvania cancer diagnostics company, and Dallas-based Galt Medical, a medical device company. He succeeds **Tom Goodman**, a former vice president of business development at Arizona Technology Enterprises—the tech transfer arm of Arizona State University and the Arizona Biodesign Institute—who left the agency in June after one year. CPRIT says it has awarded 27 product development grants totally more than $250 million since the agency was founded in 2009.

http://www.xconomy.com/texas/2015/11/19/michael-lang-to-head-product-development-for-texas-cancer-agency/

HOUSTON BUSINESS JOURNAL

Major CPRIT grant brings San Francisco pharma company to Houston

Joe Martin Nov 20, 2015,

San Francisco-based Ruga Corp. plans to relocate to Houston following a $20 million grant from the Cancer Prevention and Research Institute of Texas.

Ruga is a biopharmaceutical company that focuses on targeted cancer treatments. The company currently has two clinical candidates in its pipeline, according to its website.

It was announced Nov. 19 at a CPRIT Oversight Committee meeting that Ruga plans to relocate to Houston following its acceptance of the grant, CPRIT spokesman Jeff Hillery said.

Ruga was not immediately available for comment. The company has several investors, including Australia-based Brandon Capital, California-based Astellas Venture Management and Stanford Management Group, according to its website.

CPRIT was created as a mechanism to bring companies from outside Texas to develop their technologies and drugs in the state. The program has helped create and grow companies in Houston, such as San Diego-based DNATrix, which was awarded $10.8 million from the institute, and many other cases, as well.

http://www.bizjournals.com/houston/blog/2015/11/major-cprit-grant-brings-san-francisco-pharma.html

DALLAS/FORT WORTH
DHEALTHCARE Daily
THE BUSINESS OF HEALTHCARE IN NORTH TEXAS

CPRIT Awards UT Southwestern With $19.6 Million In Grant Money

by Matt Goodman 11/24/2015

UT Southwestern won nearly $20 million in grant money from the state's cancer research institute that will fund initiatives headed by 17 investigators.

The Cancer Prevention and Research Institute of Texas gave the academic medical institution $2 million earlier this year to go toward recruiting efforts. Now, the state has funneled $19.6 million—which came from a pool of $112 million in grant money—to its researchers, who will use it to study preventive, diagnostic, and therapeutic services for cervical, breast, lung, colon, and pediatric cancers.

The heftiest grant went to Dr. Michael White; he got $3.9 million that will go toward training future cancer researchers at the university.

"These awards deepen UT Southwestern's capabilities to reduce the burden of cancer in Texas and among people everywhere. Most notable is the recognition by CPRIT of our training program, led by Dr. Michael White, as exceptional, and the $3.9 million award to train the next generation of cancer researchers," read a statement from Dr. James Willson, Associate Dean of Oncology Programs at UT Southwestern, and Professor and Director of the Simmons Cancer Center.

In all, UT Southwestern has received $316.3 million from CPRIT since Texas voters approved its creation in 2007. Head here for more details about the projects this money went to.

http://healthcare.dmagazine.com/2015/11/24/cprit-awards-ut-southwestern-with-19-6-million-in-grant-money/

AUSTIN BUSINESS JOURNAL

JANUARY 22, 2016

PEOPLE ON THE MOVE

▸ MOVING UP

JAMES WILLSON

CHIEF SCIENTIFIC OFFICER
CANCER PREVENTION AND
RESEARCH INSTITUTE OF TEXAS

Dr. James Willson has been named chief scientific officer of the Cancer Prevention and Research Institute of Texas, effective March 1.

Willson replaces Dr. Margaret Kripke, who retired after serving as CPRIT's chief scientific officer since 2012.

Willson will lead CPRIT's academic research program in supporting innovation in cancer research and recruiting world-class cancer researchers to Texas institutions.

"With Jim's addition, we have the team in place to accelerate CPRIT's momentum," said CPRIT CEO Wayne Roberts in a statement. "He'll catalyze basic cancer science and synergize translation of scientific discovery into therapies to prevent, mitigate and cure cancer."

Willson is currently director of The University of Texas Southwestern Medical Center's Harold C. Simmons Cancer Center and associate dean of oncology programs. He is a practicing oncologist and nationally renowned for his work in the genetics of colorectal cancer, having spent more than 30 years in the field.

"I was attracted to this position because it provides an opportunity to expand the frontiers of cancer research by encouraging new discoveries with real potential to transform the way cancer is treated," Willson said.

Prior to joining UT Southwestern in 2004, Willson spent 10 years as the director of the Case Comprehensive Cancer Center in Cleveland.

Willson did his undergraduate studies at the University of North Carolina, Chapel Hill, and earned his MD from the University of Alabama in 1976.

THE CANCER LETTER

Willson Named CPRIT Chief Scientific Officer

Jan 22, 2016

JAMES WILLSON was named chief scientific officer of the **Cancer Prevention and Research Institute of Texas,** effective March 1. Willson is the associate dean of oncology programs, and professor and director of the Harold C. Simmons Comprehensive Cancer Center at UT Southwestern Medical Center.

Willson led UT Southwestern's successful efforts to have the Simmons Cancer Center recognized with comprehensive status from NCI, the institute's highest designation, according to the university.

"I was attracted to this position because it provides an opportunity to expand the frontiers of cancer research by encouraging new discoveries with real potential to transform the way cancer is treated," said Willson, who holds The Lisa K. Simmons Distinguished Chair in Comprehensive Oncology at UT Southwestern. "I look forward to building on the exceptional contributions and high standards of excellence of my predecessors – Drs. Margaret Kripke and Al Gilman."

As chief scientific officer at CPRIT, Willson will lead the agency's academic research program in supporting its research and recruiting cancer researchers to Texas institutions.

To date, CPRIT has awarded 806 academic research grants totaling $1.046 billion, and CPRIT funding has helped hire 104 cancer researchers in Texas.

"Dr. Willson has provided outstanding leadership as Director of the Harold C. Simmons Comprehensive Cancer Center at UT Southwestern, as reflected in the enormous growth of both its groundbreaking research program and superb care for cancer patients," said Daniel Podolsky, president of UT Southwestern.

"CPRIT and the State of Texas are fortunate that Dr. Willson will bring his great expertise and experience to the vitally important position of Chief Scientific Officer. We will be forever grateful for his contributions to UT Southwestern over the past decade and wish him well in his new role."

The late Nobel Laureate Alfred Gilman, regental professor emeritus, former chairman of pharmacology and dean of the UT Southwestern Medical School, as well as former executive vice president for academic affairs and provost at UT Southwestern, served as CPRIT's first chief scientific officer. Willson will replace Kripke, who retired after serving as CPRIT's chief scientific officer since 2012.

Willson has spent more than 30 years in the field and is renowned for his work in the genetics of colorectal cancer. His research led to the development of cell and animal models for human colon cancer that have been key to identifying genetic factors in disease progression.

His most recent research focuses on identification of novel molecular targets for cancer therapy. In 2015, he led a collaborative team study that identified a molecule that may play a significant role in accelerating cell recovery following bone marrow transplants, liver disease, and colon disease.

Willson joined UT Southwestern in 2004. He helped oversee expansion of research and clinical facilities at the North Campus, expansion into Richardson and into Fort Worth at the Moncrief Cancer Institute, and the oncology floor at UT Southwestern's new William P. Clements Jr. University Hospital.

Prior to joining UT Southwestern, Willson spent 10 years as the director of the Case Comprehensive Cancer Center, which also received a top NCI designation during his tenure.

http://www.cancerletter.com/articles/20160122_4

Texas Cancer Agency Names James Willson Top Science Officer

Angela Shah January 29th, 2016

Xconomy Texas — The Cancer Prevention and Research Institute of Texas has a new chief scientific officer: James Willson.

Willson comes from the University of Texas Southwestern Medical Center and had also spent a decade as the director of the Case Comprehensive Cancer Center in Cleveland. I spoke with him this week as he prepares to move to Austin to assume the state agency post by March 1.

"I've been a leader of a cancer center in two different communities and have participated in building the infrastructure in the university setting," Willson says. "Now I have the opportunity to use those talents on a larger scale across Texas."

Willson says one of his first items of business in the new post is to go on a "listening tour" with scientists and officials at the state's top cancer institutions. "With the president's State of the Union, this is the golden time for taking next steps in terms of cancer research and translation to impact patients," he says. "It's an opportunity for cooperation not only within Texas but across the nation in terms of leveraging these precious resources."

CPRIT, as the agency is known, started in 2007 with a 10-year mandate to invest $3 billion of taxpayer money for cancer-related research, drug development, and prevention in Texas. Since inception, the agency has given out 806 research grants totaling a little more than $1 billion, 104 researcher recruitment grants for $308.1 million, 28 product development grants of $270.1 million, and 158 prevention grants of $155.4 million. (The agency was put on a **yearlong hiatus** in 2012 following legislative and criminal scrutiny over improperly allocated grants.)

Willson succeeds Margaret Kripke, who became the agency's top scientist in 2012 and announced her retirement last year.

While Willson's new role comes with a focus on boosting academic research, he says he plans to work with the agency's commercialization staff to help translate that research into viable therapies. "We're bringing new talent and new ideas from across the country in building the next generation of cancer researchers and physicians," he says. "We're looking to build the opportunities for taking the fruits of that discovery into impacting patients."

http://www.xconomy.com/texas/2016/01/29/texas-cancer-agency-names-james-willson-top-science-officer/

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS, CPRIT SR. STAFF
FROM:	REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	2015 CONFERENCE EVALUATION REPORT
DATE:	FEBRUARY 8, 2016

The fourth CPRIT Innovations in Cancer Prevention and Research conference was held November 9-10, 2015 at the Renaissance Hotel in Austin, Texas. The following is a report on attendance, registrant survey results and budget for the conference.

Registration and attendance

Eight hundred twenty three (823) people registered for the conference, 29 of which were CPRIT staff. Of the 757 that answered the question about which track they were interested in attending, 490 indicated they were interested in attending the academic research track, 122 the product development track and 145 prevention.

Survey results

A conference survey was available onsite and also online. Two hundred thirty eight (238) responses were received. The key points and themes are summarized here and the entire report with detailed feedback is attached.

Of the 238 respondents, 144 (60.5%) indicated they mostly attended the academic research track, 51 (21.4%) the product development research track and 74 (31.1%) the prevention track.

Satisfaction with the conference content and speakers

The feedback regarding the content and speakers was overwhelming positive. One theme that emerged from the comments is that the respondents (the majority of whom attended the research track) wanted more academic research sessions, more speakers and more CPRIT Principal Investigator presentations.

We specifically asked for feedback about the plenary sessions. They were all very well received. Based on the volume of responses, Dr. Katz's session on the impact of diet and lifestyle received the most positive comments, followed by Dr. Kripke's panel on immunotherapy.

Comments about the poster sessions were also positive. Suggestions included ensuring that posters stayed up the entire time and having access to the abstracts before the conference so that they could determine which they wanted to see in advance. There were also a few that suggested having the abstracts in an electronic format instead of in print.

We also asked for suggestions on future topics and speakers and received many ideas to consider in planning the next conference.

Conference format and location
When asked about the conference format they preferred, 77% preferred a combination of plenary and breakout sessions and 23% indicated they preferred separate tracks for the entire conference. Plenary sessions ranked first in order of importance, followed by poster sessions and networking. The preferred length for the conference was 2 days (79%).

In terms of location for future conferences, 39% preferred Austin, 24% Houston, 18% San Antonio, and 17% Dallas. Fort Worth and McAllen each received one vote in the "other" category.

Logistics
Themes emerging from the feedback on the conference logistics indicated they would have liked more time for audience Q&A and networking. Several voiced displeasure at some of the sessions running over the allotted times. Two comments were received about the need for audio or video recording of the sessions. We eliminated that from the budget due to cost but will explore adding it in the future.

Some dissatisfaction with the food quantity and quality was voiced. Many suggested the conference should provide breakfast or at least coffee before the program starts. Healthier food options were also suggested. We budgeted conservatively and only provided for a mid-morning coffee break, lunch and a mid-afternoon coffee break each day.

There were significant challenges in our dealings with the hotel and their lack of customer service. While we were able to mitigate many of the issues, others did affect the attendees and are reflected in their comments.

Budget
Revenue from registration was projected to be $222,850, projected actual revenue is $245,950. Included in the projected actual revenue is approximately $9,000 in purchase orders we anticipate collecting. Projected expenses were $311,292 and projected actual expenses are $227,748. Included in the projected actual expenses is an estimated additional $1,000 in expenses that have not come in yet. The major expense variances (savings) from budget were in vendor costs, and food and beverage. We had also added $10,000 for unexpected expenses and only used $923. In summary, the net revenue collected from the conference is estimated to be approximately $18,000.

Receipts from the conference are deposited into the General Revenue Fund into an account earmarked for the conference. There is authority in the state budget (General Appropriations Act) to carry forward any balances earmarked for a specific purpose and continue to use them for that same purpose. Therefore, we will be able to use the remaining revenue for the next conference.

Summary and Recommendations

By all accounts, the 2015 conference was a success. Attendees and speakers were favorably impressed with the quality of the conference and happy to see that CPRIT has resumed this event.

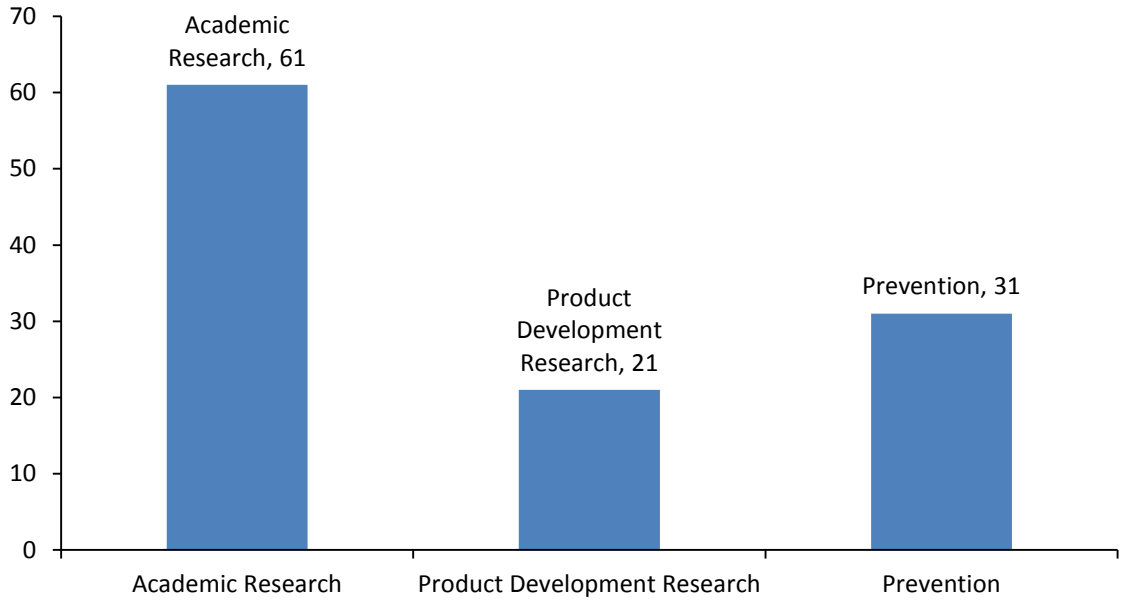
We were conservative in developing the budget for this event but, given this years' experience, we can consider adding a few features. As we begin planning the next conference, I recommend we explore pros and cons of the following:

-Planning a full 2 days' worth (~14-15 hrs.) of programming but spreading it over 3 days. For example, start the afternoon of the Day 1(3-4 hrs.), have a full day on Day 2 (7 hrs), and half day on the morning of Day 3 (3-4hrs.)
-Increasing the budget for food and if needed, increasing the registration cost
-Increasing formal networking opportunities
-Audio recording of at least some of the sessions
-Providing an electronic, searchable version of the abstracts in advance of the meeting

INNOVATIONS
In Cancer Prevention and Research Conference

Conference Survey

1. Which breakout track did you mostly attend?



Value	Percent	Count
Academic Research	60.5%	144
Product Development Research	21.4%	51
Prevention	31.1%	74
Total		238

Statistics

Total Responses	238

2. Give us your feedback about the sessions you attended in this track, both positive and negative.

Keynote/Plenary Feedback

- The plenary talks are informative and educational.
- The opening panel with Allison was excellent, as was the panel on HCC
- Environmental factors for carcinogenesis talk was very good.
- Great plenary sessions and update from research.
- First session was great. Well organized and developed. The panel was interesting - particularly Dr. Allison's comments. Second session was interesting. –

- About facilities - the rows were very long and it was difficult to get out to ask questions. More aisles would have helped that room. The commercialization session went too long with too little meaningful content.
- Plenary sessions should be catered more generally rather than scientific focused. More options for the breakfast sessions.
- Plenary sessions targeted research and didn't apply to prevention or product development attendees
- Plenaries were very general, described problems without more detail on potential solutions. EPI talks were good, with interesting work.
- The "Environmental Chemicals and Breast Cancer: What do we know" talk by Dr. Brody was terrible. Not a very well organized or delivered talk. The "Liver Cancer in Texas: Causes and Cures" session with Dr. El-Serag and Dr. Turner was very good.
- There may have been logistical reasons for this, but I found it puzzling that Jim Allison, a recent recipient of the Lasker Award, was given only twenty minutes to speak in comparison to certain later speakers who did not give talks nearing the same quality
- A workshop format would have been more useful. Keep it very clear and simple: these are the steps necessary to get from idea to license.

Posters

- Poster sessions were great, in-the-hallway meetings and meeting colleagues at meals was great.
- Some poster presenters did not show up in front of posters.
- The talks were fine. The poster session was less well done. Shorting the poster time Tuesday was disappointing.
- I enjoyed the scientific sessions. I found that several sessions ran late and the seemed to eat into the time for the poster sessions. Given the number of posters, more time could have been allotted for the poster session.
- The talks were interesting. Poster sessions were organized very well and covered a variety of subjects from cancer biology aspects to clinical subjects and model systems.
- Having multiple high-caliber scientific posters was a great plus.
- Poster sessions were very useful and resulted in proposing new collaborations.
- Poster sessions are too big. Have less on each day and more time, cluster them?
- I thought attendance at the poster sessions, particularly the first one was light in that not as many people were browsing the posters

Academic Research

- Academic sessions are very good. I learned lot about cancer immunotherapy. Product development talks are impressive.
- I would like to see more research talks.
- They were good, but the academic track research was a bit unorganized, and the speakers were lacking. It would be nice to subdivide speakers into sessions based upon their topics (i.e. one session on transcription factors, one section on microenvironment, one section on therapeutics, etc.). It would also be better to have more speakers attend - make it mandatory that PIs receiving a certain amount of money come and present their research. Many big name CPRIT funded PIs were not even at the conference. Also, some emphasis on student development would be nice
- Would have been nice to have more sessions about Academic Research. Could be organized around the topics used to organize the posters.
- I enjoyed the academic research track and found the selected talks very enjoyable. I felt that this track was limited in the number of presentations. I felt it may not have been an accurate representation of all the ongoing CPRIT funded research in the field of cancer.
- Research talks by CPRIT grantees were generally good. My only complaint was a tendency for some talks to go overtime and infringe upon Question and Answer, poster sessions, etc.
- Good coverage of the science that CPRIT is funding. Less coverage of how investigators succeeded in securing CPRIT funding.

- I like cancer immunology session and CPRIT scholar research activities session at second day of the conference.
- I attended most of the research sessions which were excellent. It could have been useful to have some sessions with shorter talks to give a wider range of research topics for CPRIT funded research.
- More Basic Science research should be included in this conference
- Talk by BCM MIRA on HCC was outstanding.

Prevention

- Prevention sessions had a good mix of topics.
- Prevention sessions were very informative.
- The prevention sessions were very helpful and informative.
- I thought the prevention grants session on day 2 at 1p was very helpful with great information. This session probably could have been longer b/c there were many questions. I attended the dissemination and implementation session on day 1 and thought the presentation was very well done. I think the content would be best suited to an audience less familiar with D&I/research. A second session geared toward an audience more experienced in D&I would have been helpful. I think presenting a case study would also be helpful.
- Relevant information for adapting programs, disseminating information, especially helpful was the talk specifically about the prevention for Application on day 2
- Although they were interesting, many of the prevention talks were not relevant to my primary focus in academic research. However, I am interested in industry and biotech companies and I did like how some of the sessions were describing how they took their research and brought that into the industry field.
- I would have liked the prevention networking session to include a community program group.
- I enjoyed all sessions but particularly the prevention and practice academic community collaborations and implementing programs in rural communities in addition to the elements of successful prevention applications.
- All of the prevention sessions were very well planned, implemented and provided useful information.
- Dr. Nancy Lee was especially good at providing unvarnished advice on "elements of successful prevention applications"; need to see more sessions offering this type of hands-on, rubber-meets-the-road specific feedback.
- Dr. Brody's slides were not very intelligible; all other prevention topics were excellent
- More sessions on prevention and possibly prevention research
- Excellent - very helpful in terms of planning and implementing CPRIT prevention projects.
- The sessions were excellent. Hearing from Becky and Ramona was especially helpful.

Product Development Specific

- Workshop on CPRIT applications for product development was spectacular. The scientist from the biotech company was exceptional and he even stayed after for an hour answering questions and providing other tangible insights into how to build a strong critical path and application.
- The product development talks were both relevant and practical with many constructive anecdotes as teaching tools; however, the format was too unstructured, and a bit discursive. A list of questions culled from input from stakeholders in advance and perhaps projected for the audience to see throughout the session in a format with defined time windows for an overview (e.g., 10 min), the pre-determined high-interest questions (30 min), and open Q&A from the audience (20 min) would be preferred. A follow-up summary from CPRIT that captures this information and shares it with attendees would have important lasting value.
- Was great to hear about their experiences. Migrated into a pep talk to bring business to Austin while Houston has the same opportunities. CPRIT is for good of Texas and planning for a hub defeats this venture.
- All the Product Development Research track sessions were very informative and helpful.

Organization

- Presentations were way too long. Sessions should be structured to include more diverse and shorter talks.
- Should be more Speakers and Speakers should be given more time. These are very technical talks and can require 15 mins just to give the background that makes the very interesting new matter more intelligible. Most Researchers are used to 2+ hr. sessions at other meetings - ok to go longer
- Very disparate talks in general and need to be reorganized. More focused talks with common interest for each sessions will be better in the future such as (Research): - Immunotherapy - Targeted therapies - microRNA & ncRNA, lcRNA.
- Though the presentations were informative, little time was reserved for audience interaction. I would like to see more time allotted for discussion and Q&A.
- More talks would be appropriate (say 10 minute ones). Having the poster abstracts beforehand would help us organize visiting the relevant posters. More variety in talks, and more coverage of institutions/labs, and not talks from the same lab.
- The time allocated for plenary sessions is short. I had an impression that some couldn't include enough information due to the time constraint, and some tried to rush through too much information in a short time.
- Length of talks was OK. Maybe consider 5 minute, rapid-fire talks, a format that allows more speakers focused on the key points and future plans/needs and less detail about formulas, etc. that can be viewed on posters or discussed later.
- I definitely enjoyed hearing about emerging and up to date research. I wish there was more time allowed per session as I felt things were rushed and there wasn't enough time for questions.
- It's a great meeting, with outstanding speakers and programs. It also provide a great opportunity to meet fellow cancer researchers in the state, form new collaboration relationship.
- They were very informative and thought provoking. I have a better appreciation of the need for collaboration between academic communities.
- Overall interactive discussions with panel members. I suggest however, to stick to the timeline indicated in the agenda. Some sessions started 15 min late and run way over the time allocated.
- The session was very well timed, both for presenters and for discussion. However, there is possibility for including more diversity in the topics of discussion in terms of translational research.
- Great speakers. Next time please make sure speakers stick to time. Some of the talk ended well after their time, which hurts the amount of time for poster sessions.
- Timing was way off for some of the scheduled talks which led to confusion. For example poster session on Tuesday was supposed to start at 10:30 but the prior talk did not end till 11.
- Great opportunity to learn from others and understand the full spectrum of what all CPRIT is doing.
- Sessions were interesting but there was irregular attention paid to timing so it was hard to keep track of when things were to start and end.

General Comments

- Each of the sessions were very informative and provided adequate information regarding new developments and research methods to obtaining favorable outreach outcomes. They addressed the current issues with presenting information in a matter that was receptive to the community and also addressed some issues with getting the medical community to take a more proactive approach to facilitate in educating patients.
- I found all sessions I attended to be quite educational, covering broad range of cancer models...each offering unique perspective.
- I found there was good variety in terms of topics discussed. I most appreciate the session about submitting a grant and the session about prevention programs in rural communicates.

- Seems like most people care more about the treatment than the mechanisms of the cancers. I think we should all know that the studies of mechanisms are equally important to treatment and that better understanding of the mechanisms can promote the development of drugs.
- Excellent speakers and information. I really feel like I benefited from the CPRIT administrators presentation regarding grant writing and what grant reviewers are looking for. I appreciate the question and answer portion of the presentations. I would like to see more of CPRIT administrators conversing with the grantees regarding reporting and billing as well.
- Well attended and I learned a lot about others are doing about specific challenges. I appreciate the panel Q&A after they talk about what their program is about.
- All the talks I attended were excellent. They were well organized and I cannot think of any negative comments.
- Research advance: updates from CPRIT grantees are reasonable. Prevention in Practice: Academic-Community Collaborations is too basic and did not see many contribution to community.
- Sessions were good. I think we need less panels and more topic based presentation clusters. E.g. if the staff pick 3 Croc projects, 10-15 minute presentations and then have a panel to discuss future directions or lessons learned. Then repeat for breast or cervical or other, etc.
- I learned of some interesting developments, and selected talks were good talks and well attended. I would rather have more short format talks incorporated into the program, and I would rather have had more poster sessions that are separated and on each topic, and last for at least 2 hours each.
- Generally informing at rather high levels. For those in industry with limited or aged experience in righting grants, a session covering logistics of the application process in some detail would have been useful.
- Good selection of speakers and the sessions were well organized. However, the screen in Ballroom was a bit small for people sitting at the back.
- Very useful evidence based knowledge about real and relevant experiences on how things work in rural areas.
- The talks were interesting and a good variety. A great choice of speakers. Good to hear updates on grant recipients' progress with their research
- The speakers were animated; which made the talks appealing to parts of the audience with diverse backgrounds. - staying on time
- Some sessions were great, while others needed improvement. Some of the panel discussions could have used better direction from the moderators, with time limits on the speakers\' responses to move things along. It also would have been helpful to have some panels for more advanced attendees, and other panels for novice attendees.
- I commend the planning committee for this Conference. The content of the plenary and product development presentations were excellent. Moreover, the sense of collaboration opportunities between researchers and product developers was ever present. CPRIT is alive and well and is a critical and needed part of Texas' role in eradicating cancer and for elevating Texas as a leader in cancer prevention, research and product development. I urge CPRIT and the Texas lawmakers to put the pedal to the medal.
- The quality of the speakers is superb. I wish there were more time allotted for questions from the audience.
- Thoughtful and topical. Overall the topics covered were relevant to current and aspiring CPRIT grantees.
- Most of the presenters were very entertaining and informative. There were a few that were highly technical and very dry presenters.
- Talk on endocrine disrupters was a lay talk aimed at 7th graders. Very disappointing. Room was ridiculously cold, too.
- Sessions were good and generally well-organized. I didn't feel the breadth of cancer research in Texas was fairly represented. There is a lot of valuable research from the physical sciences/bioengineering (i.e. radiation therapy, HIFU, RF ablation, etc.,) that was absent from the conference which is a shame. Especially since one of the over-riding messages from many of the plenaries was the need to think inter-disciplinary!
- Interesting conversation and insight from CEO’s. Too long. Academic Research Session was very interesting and enjoyable.

- The sessions were very interesting. I especially appreciated the session with CPRIT funded companies.
- Elements of successful...was disappointing could have been shorter. Since some sessions are on a parallel track it would be helpful to have access online to talks
- The session were very informative, and I learned a lot. I am glad that the conference provided a broad array of topics, and that I was able to learn able all of the different efforts that support the cure for cancer.
- Very good content perhaps the next year make sure that each session/speaker has an abstract describing the content and context for the session.
- The session on HPV was informative and persuasive. The session on moving from research to dissemination was mundane.
- The breakout sessions attended were insightful and informative especially for a new grantee. I especially enjoyed the CRC Collaborative Session on Monday evening with Dr. Foxhall.
- All sessions were great and informative. Overall, I thought the conference was better than the last one. David Katz was phenomenal and inspirational!! So happy you invited him to speak to CPRIT.
- The sessions I attended were very good and informative. The speakers/panelists were very approachable. It did seem somewhat Austin centric for some session, but they were still good.
- They were very informative. I liked the speakers and the content of the research they shared. New methods of treating cancer.
- I liked how broad it was, however I felt as if each particular session could be more unified in theme.
- The breakout sessions contained excellent and useful materials. Great moderators and presenters.
- It was a great opportunity to share successful experiences and also the challenges that we all experiences in our fields and communities very good experience!
- I attended the first plenary session Monday and the round table of start-up companies Tuesday. I also saw Dr. Gerogiou on Monday afternoon. All presentations were impressive.
- I thought the plenary research speakers were engaging presenters. I especially liked George Poste, PHD. I think his presentation was right on about precision oncology will be the methodology that will lead to cures for cancer.
- The topics are very interesting and relevant. The speakers have delivered great presentations and Q&A.
- This was my first year attending and I thought all the sessions were great! All sessions presented the purpose of their talk in a clear and concise manner.
- Would be great to see a CPRIT portfolio so we can learn who else in our shared scientific space may have assays or models that we could collaborate effectively. Rob Sarinsky did an outstanding job at helping to instruct how to improve the application process, by providing tangible examples. Thank you for having a biotech expert address this need.
- I thought all of the session were great. As a mental health professional who works in tobacco cessation, some of the presentations went way over my head. It would have been nice to be able to understand some more, but I also understand that I may have been in the minority of not being able to understand due to my education background and the work that I do. In fact, it was pretty neat to sit in a room with people talking about innovative and cutting edge cancer research information, even if some of it went over my head.
- All positive except cell phone interruptions
- All sessions were quite good.
- Difficult to see screen from back
- Excellent--3
- Excellent combination of presentations and discussions.
- Excellent major presentations. I learned a great deal of new information.
- Excellent presentation and networking opportunities
- Generally breakout sessions were good.
- Good--4
- Good overall - one session highlighting nuts and bolts
- Good variety of speakers

- Good. A wide variety of research represented which means many talks were outside my expertise.
- Great conference! Great networking opportunity and inspirational speakers.
- Great to hear/see the work our scientists are performing.
- I attended both Academic and Products. The sessions were generally excellent and well moderated
- I enjoyed all the sessions. I felt there was little covered on next generation sequencing topics.
- I enjoyed the breadth of topics from grantees. I have no negative feelings about the sessions.
- I felt all the tracks I attended were very informative.
- I found all the sessions very informative and inspiring
- I found each topic very informative.
- I think the sessions are well organized
- It is good, but it would be helpful if there is a session about application
- It's very good. I learned the progress and some novel knowledge in cancer research.
- Largely good and informative. I would perhaps leave more avenues for the Q/A sessions.
- Learned many interesting facts.
- More time for discussion and questions
- Nice informative sessions. Slightly old data presented (2014 and earlier).
- Really exciting science!
- The presentations were mostly informative and interesting
- The reports are very informative and present the frontier of cancer research.
- Excellent speakers from companies and academia.
- The sessions I attended were excellent. Great choice of speakers.
- The sessions were informative and targeted to the projects I work on.
- The sessions were so informative.
- The talks was very well performed.
- The talks were comprehensive and I learnt a lot of the new findings about cancer research.
- The talks were informative but too broad and long at times
- These sessions were great! Especially for those that have not yet submitted an application.
- They were all valuable. Dr. Katz was a standout.
- They were great! Very good speakers and up to date information. I enjoyed them all.
- Topic too broad
- Topics were too broad to have a devoted interest.
- Very good. I would like to hear more on how they overcame barriers
- Very informative.
- Very well.
- Good quality of talks and presentations
- Informative and focused
- Too few talks

3. Give us your feedback about the plenary sessions you attended (Dr. Kripke's panel, Dr. Katz, Dr. Poste, and Dr. Sandler), both positive and negative.

<u>Comments related to all plenary sessions</u>

- Great and inspirational -
- Dr. Jim Allison was excellent as was Dr. Malcom Brenner. They both needed more time to discuss their ideas and experiences. While Dr. Katz was entertaining, his session was a bit superficial.
- A review of the biological/ chemical of cancer that lead to drugs or immunizations were excellent. However, Dr. Katz's presentation about obesity and it's role in cancer was passionate and his plea needs to be taken more seriously by everyone including CPRIT
- All are excellent. Dr. Kripke is an excellent moderator. Dr. Katz's speech is impressive.
- All fine.
- all great talks
- All of the plenary sessions were great. Drs. Poste and Katz were exceptional
- All the speakers had so much educational information on all their presentations and all the sessions were very interesting.

- All were very informative and contained a reasonable amount of useful ideas and some backing data.
- Allison - easy to understand the why Katz - wonderful speaker with a message
- All plenary sessions were satisfactory
- All talks are exceptional.
- Decent
- Did not attend
- Dr. Katz and Dr. Sandler's sessions were not as relevant to this conference of scientists and could be shorter talks/swapped for basic research talks Dr. Kripke and Dr. Poste's sessions were very good
- Dr. Katz was extremely effective in his approach to explain the epidemic of a dying society, or a society that has chosen to die because of lifestyle. I also appreciated the information provided by Dr. Sandler & Dr. Kripke. The only negative I can think of, is a larger time frame to allow ample opportunity to ask a few more questions. Also, the mics were only in one isle, it would have helped to have one mic in each isle so that we didn't have to sprint from either side to ask our questions before we ran out of time.
- Dr. Kripke's panel session was very interesting. Dr. Katz was entertaining but I would have preferred more real science. I was disappointed in his self-promotion.
- Dr. Kripke session was amazing. It was very informative and great Q&A. Special mention to Dr. Allison for giving such a good talk. Dr. Katz was excellent, made us think.
- Dr. Kripke's panel and Dr. Katz were great.
- Dr. Kripke's panel was excellent, even though I couldn't understand all of it. Her questions were very informative. Dr. Katz seemed odd. He seemed to be promoting himself. I think most of the audience already knew the content. I would have appreciated his talk more if he had pitched his talk more to an audience of experts.
- Dr. Kripke's panel: Excellent data regarding new emerging concepts in immunotherapy of cancer. Dr. Katz: entertaining too parochial in nature. Dr. Poste: The best presentation. Captivating. Dr. Sandler= A good presentation dealing with the complexity of Hepatitis virus.
- Dr. Kripke's panel - excellent; Dr. Katz - entertaining; Dr. Poste - excellent; Dr. Sander - excellent; Dr. Brownson - very good; Prevention in Practice with Wyatt - excellent
- Dr. Kripke's panel on immunotherapy was scientifically the highlight of this meeting. Dr. Katz is a great entertainer. Dr. Poste made a heroic effort to summarize big data in 45 min (not sure it could have been useful given the topic), and Dr. Sandler's talk was clearly helpful in spreading the word on vaccination and inspirational as well.
- Dr. Sandler was very informative
- Drs. Sandler's and Poste's were outstanding.
- Excellent plenaries. Dr. Katz was amazing so was Dr. Poste. More time for discussions / questions would be good. I really liked the panel format afterwards to continue the discussions
- Excellent sessions. More q and a time would be nice
- Generally good overviews of the complexities and issues contained in tackling cancer
- Great - learned so much.
- I attended and enjoyed all plenary sessions but particularly Dr. Allison, Dr. Katz, Dr. Poste and Dr. El-Serag.
- I attended all these sessions and they were very well organized and informative.
- Great! Turn off cell phones- do it as a group exercise at start of each session
- I attended all of the plenary sessions. I enjoyed the variety of topics that these talks covered.
- I attended all the plenary sessions and found the topics been presented very thought provoking. I felt the topics been presented were well covered. I have nothing negative to say about the plenary sessions.
- I very much enjoyed the plenary sessions and panel discussion afterwards.
- I wasn't able to attend the plenary sessions so cannot comment on these.
- I wish there were more time allotted for questions from the audience.
- immune therapy very good; Katz talk good but he wasted time reciting poetry and going over-time
- Immunotherapy - great talks, need broader intro first. Katz was important to have as was. Poste for perspective.

- Kripke - boring but a few good slides. Katz - entertaining, many interesting slides. Poste - very general, wanted more Sandler - too long
- Dr. Kripke was excellent
- Kripke - good Katz - good
- Kripke's - very good (Allison superb, Brenner - good, Yee - rushed), Katz - outstanding, Poste - very good/thought provoking/challenging Sandler - good message, wrong audience
- Kripke's panel - OK Katz - Excellent Poste - Excellent Sandler - Painful
- Dr. Sandler - great talk, very helpful Dr. Katz - great speaker, but what about alcohol?
- Dr. Allison's presentation was very informative - highlighting the promises and challenges using checkpoint blockade therapy. Dr. Katz's presentation challenged me in a very pragmatic manner that power is in applying what I know not how much I know..
- Dr. Sandler's talk on HPV vaccine left a deep impression on me, the others\' talks were also profound
- Not TX specific enough. Katz was amazing. Sandler's HPV info was old and outdated and nothing new
- Outstanding and inspiring
- • Plenaries overall were good, however it would have been good to have someone from NIH provide a 2025 vision and the NCI session was a miss, the conference is about cancer research progress not lack of vaccinations.
- Plenary speakers were excellent and gave truly enjoyable talks. All were unique but elevated the conference. I would have liked more time for discussion after each one since they brought up broad topics that the whole Texas cancer community could have discussed.
- Plenary talks were simply outstanding and of the highest quality (Allison, Katz, Poste). These presentations could go toe-to-toe with any tier one meeting anywhere in the world. Hats off to the organizers for coordinating this elite agenda of high-impact--and highly current--topics.
- Plenary topics were terrific; speaker delivery and content was disappointing. Dr. Katz talk could have been half as long and less self-promoting. Kudos for an environmental session; unfortunately, Dr. Brody was an uninspiring representative. Dr. Sandler spent far too long explaining the President's advisory panel and no time showcasing the CPRIT-supported work about exactly why we have lower HPV vaccine uptake. Not helpful.
- Positive Plenary sessions for me were: Jim Allison, MD David Katz Julia Brody George Poste
- Presentation of Dr. Katz and Dr. Poste left a deep impression on me.
- presentations were good
- Really enjoyed David Katz\' presentation and the HCC presentation.
- Same comments as in 2 above. Sessions were enjoyable and interesting but would have enjoyed hearing more hard science.
- Sessions were cutting edge and engaging. Having cutting edge researchers such as the starting panel was great.
- Since I am not involved in research or product development, I found Dr. Katz' prevention presentation the easiest to follow, but I'm sure most in the audience were pleased with all presentations.
- Superb
- Talks by David Katz and Dr. Poste were outstanding. Really learned a lot.
- The "Modern Epidemiology: Dark Wood, Glimmer of Hope" talk by Dr. Katz was good and entertaining. I really liked the immunology panel hosted by Dr. Kripke.
- The caliber of the speakers was of such high quality. Very impressive work was presented.
- The panel was fascinating and well done. Dr. Katz was terrific. Dr. Poste & Dr. Sandler were interesting.
- The panels were diverse in content, but successfully provided multiple viewpoints of the challenges cancer research faces from various experts in the field. Given the potential for audience access to these experts, little time was devoted to audience interaction. If break-out panel discussions were available later in the day following each respective talk, I believe many attendees would have taken advantage of having access to prestigious leaders in the field.
- The plenary sessions are very difficult to evaluate. As a non-physician, nonscientist, I got the most out of Dr. Katz and Dr. Sandler's presentations. Frankly, I multitasked during Dr. Kripke's panel and skipped most of Dr. Poste.

- Katz was outstanding. Poste outlined the problems; it would have been good to have some brainstorming about the solutions.
- Katz's was my favorite followed by Immunology panel....both excellent
- The plenary sessions were a highlight of the meeting.
- The plenary sessions were excellent! I particularly enjoyed Dr. Katz\' speech.
- The plenary sessions were not as interesting.
- The plenary sessions were wonderfully relevant to a lot of current development in the field of immunotherapy and treatment. Dr. K especially was a fantastic speaker tying cancer fluidly to current issues of unhealthy lifestyles and behaviors that contribute so much to cancer and other chronic disease as well.
- The sessions and speakers were all informative
- These were fine
- They were great! Knowledgeable and good speakers.
- very good
- Very good speakers and talks
- Very good speakers who gave excellent talks.
- very informative
- Very informative and educative; I thoroughly enjoyed it.
- Very informative and encouraging! Great selections.
- Very interesting and easy to follow.
- Very interesting and timely topics. Very engaging speakers. Enjoyed all the plenary sessions.
- Very thought provoking.
- Very well
- Would like to see more diversity

Comments specific to Kripke Panel

- All the plenary speakers were very good and I enjoyed the panel led by Dr. Kripke.
- Kripke's panel was good. Only unfortunate that there wasn't more discussion.
- Dr. Kripke's panel was fascinating and pitched at just the right level.
- Excellent. I learnt a lot about immunotherapy from Dr. Kripke's panel discussions and the talks. Other panels were also equally great
- I attended Dr. Kripke's session of cancer immunotherapy and enjoyed all three talks.
- I attended the immunotherapy panel which was excellent and timely.
- I really liked Dr. Kripke's panel - good diversity of participants
-

Comments specific to Katz plenary

- All of the plenary talks were great and very inspirational. Dr. Katz\' talk was particularly enjoyable.
- All of them were great. Dr. Katz especially stood out. What a wonderful speaker and I really enjoyed his talk.
- All sessions were interesting ;however, for someone that is a grantee working on the prevention side I found Dr. Katz' presentation meaningful and applicable to any environment
- All talks were interesting and relevant, except Dr. Katz. While entertaining, he spoke almost exclusively about diabetes.
- All the presenters were very well spoken with excellent information to share. Because our program is Prevention Dr. Katz presentation was the most appropriate for our program and more understandable. The research being done for CPRIT is most impressive but sometimes the speakers were hard to follow.
- Although not all of them pertained to me and my work, I found them very interesting and informative. Particularly enjoyed Dr. Katz - very knowledgeable and a wonderful presenter.
- As stated above Dr. Katz was fantastic! I enjoyed all of the plenary sessions even though some were not in my area. All the speakers gave clear and informative presentations that all the audience could grasp.
- Best presentation was Dr. Katz
- Dr. Katz lecture is very entertaining and give us motivation to change our lifestyle for betterment. 6 V and 3F will do 60% reduction rate of chronic diseases in future. Dr. George Poste raised a very good point in his lecture- Do science which you can translate into clinics

and not for publication. He said that out of 12,000 proposed biomarkers in published scientific literature, only 100 used for diagnostic purposes plus lot of money goes for this research is wasted.

- Dr. Katz loved Dr. Sandler loved
- Dr. Katz session was awesome he really connect with audience and he is a great speaker
- Dr. Katz was a great speaker, interesting variety of topics. Dr. Sandler was very interesting- good to have someone from NCI speak
- Dr. Katz was awesome and inspiring
- Dr. Katz was great
- Dr. Katz was great but many of the sessions were not as generalizable as they could be the content and speakers were fine just not as relatable across the spectrum
- Dr. Katz was my favorite, he's a superb speaker. Dr. Sandler also gave an excellent talk. I enjoyed all of the sessions but these stood out.
- Dr. Katz - excellent talk! Dr. Poste - very informative
- Dr. Katz talk was very stimulating and the topic was presented in a very good way
- Dr. Katz talk stood out the most, it was inspiring and informative. I really enjoyed listening to him speak. His topic was well received, and he provided solid evidence for his ideas.
- Dr. Katz talk was fun to hear but it is not really related to cancer
- Dr. Katz was a fantastic presenter. I would like to see more speakers with strong presentation skills like those exhibited by Dr. Katz.
- Dr. Katz was a real standout.
- Dr. Katz was amazing! His presentation was by far the most entertaining and informative.
- Dr. Katz was excellent and very engaging. I would love to see what he brings to the conference in the future.
- Dr. Katz was fantastic and inspiring, Dr. Kripke was excellent
- Dr. Katz was one of the best presentations of the conference along with the immunotherapy section.
- Dr. Katz was the best for me as it was focused on prevention and is an area I am fond of learning more about. The others were out of my area of expertise and very difficult to understand or follow. The PPT slides were jammed with data/info which was too small to read from the audience. The speakers used research specific jargon that caused only those working in that area to be able to understand the message. The conference plenary sessions should be targeted at the general audience, not specific components of the audience. Or, the conference should offer other options for the audience members to attend when the plenary session is on a complex specific area.
- Dr. Katz was very entertaining all others were BORING!!!
- Dr. Katz's session was good.
- Dr. Katz's was extremely inspirational. Excellent presentations
- Dr. Katz's was very informative. Some of the other plenary sessions were "over my head" but interesting. I got the overall picture and good to see what advances research has made will all the research funding.
- Loved Dr. Katz. Very talented presenter as he captivated the people in the room. His talk came up in conference frequently among participants.
- educational although the terminology at times was way over my head
- Enjoyed Dr. Katz's presentation with the light-hearted, yet serious message.
- Great sessions. Dr. Katz did wonderful
- Great speakers. Dr. Katz 'presentation was a bit long but energizing overall.
- I believe all the sessions were appropriate in length and content. Dr. Katz was definitely very enthusiastic and passionate about his topic, it was hard not get energized to continue contributing to the cause.
- I enjoyed the discussions, the positive would be discussing form different point of view.
- I enjoyed the talk by Dr. Katz the most as it was very systematically organized and vital information was shared in a short time
- I found Dr. Katz's talk to be particularly relevant to public health and cancer prevention. He is a phenomenal speaker and this talk was a real high point for me.
- I greatly enjoyed the plenary sessions. The session on CPRIT's future was very good as well.
- I loved their presentations. They provided a lot of useful information.

- I most enjoyed Dr. Katz\' session and the session about liver cancer.
- I personally favored Dr. Katz's talk because my line of work involves behavior change. And we provide great resources to implement in a real world setting.
- I really enjoyed this session a lot. It made me be proud to be a part of the CPRIT family. To see what all CPRIT does was amazing.
- I really liked Dr. Katz talk. Very informative and inspiring talk on why one needs to have a healthy life style and balanced diet.
- I thoroughly enjoyed each of these sessions
- I very much enjoyed Dr. Katz's talk especially. I feel more data driven talks would have been nice.
- Informative and entertaining talks for wide/varied audience with good combination of big picture overview and detailed science. Could be better if talks were on more hot/controversial topics
- It (Dr, Katz) was an amazing session regarding prevention of general health. Different perspectives of prevention were presented in a simple way. However, a little attention was given to the cancer prevention.
- Jim Allison most excellent. David Katz amazing.
- Katz - great speaker; presentation was too long
- Katz - Great talk, post video and text on CPRIT website.

Comments specific to Poste Plenary

- Dr. Poste gave an excellent talk highlighting the complexity of Cancer the need to for new ways to think about treating patients. Very topical, current and informative
- Dr. Poste was inspirational
- Dr. Poste's was great and very provocative regarding personalized medicine Dr. Katz was entertaining but it was not on cancer and was not clear why was he invited for.
- I enjoyed Dr. Poste's overview of the field.

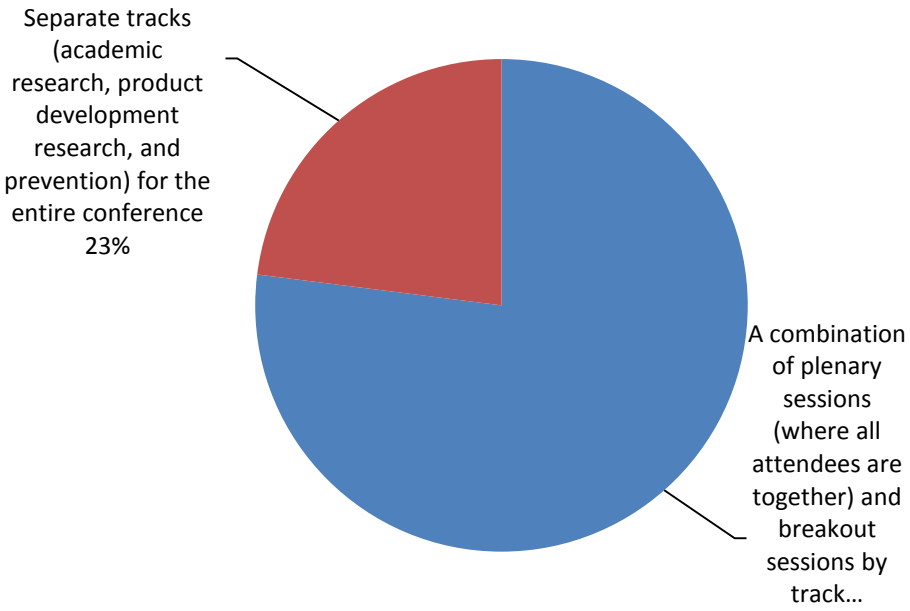
- Next time, make sure seating arrangement is feasible for audience to leave and enter at well. Ballroom A seating was terrible.

4. Rank in order of importance (with 1 being most important to you and 6 being least important to you) the following aspects of the CPRIT conference:

	Score*	Overall Rank
Plenary Speakers	964	1
Poster Sessions	853	2
Networking	802	3
Hearing progress reports from CPRIT grantees	790	4
Panel Discussions	712	5
Hearing from CPRIT leadership	675	6

Score is a weighted calculation. Items ranked first are valued higher than the following ranks, the score is the sum of all weighted rank counts.

5. Which CPRIT conference format do you prefer?

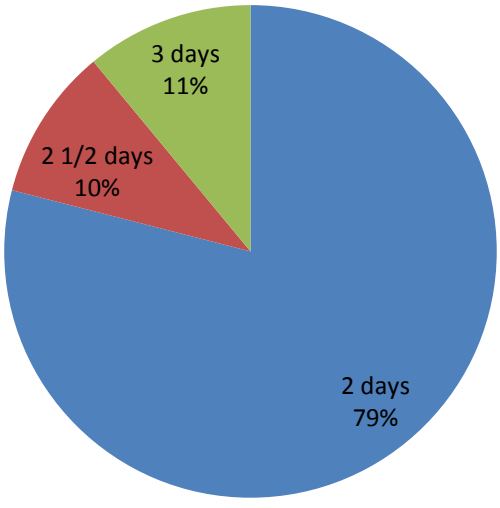


Value	Percent	Count
A combination of plenary sessions (where all attendees are together) and breakout sessions by track (academic research, product development research, and prevention)	77.0%	187
Separate tracks (academic research, product development research, and prevention) for the entire conference	23.1%	56
Total		243

Statistics

Total Responses	243

6. Preferred length for the CPRIT conference:

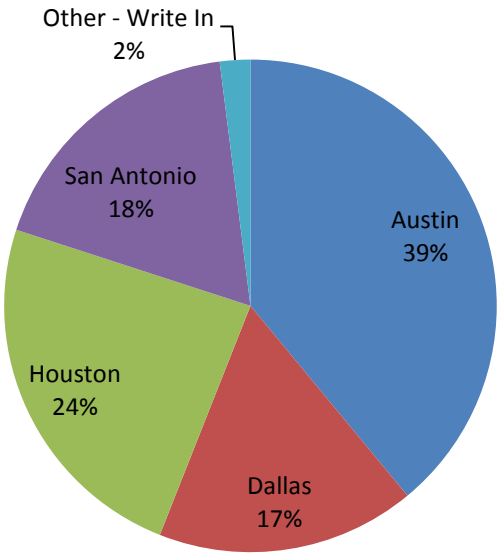


Value	Percent	Count
2 days	79.2%	198
2 1/2 days	9.6%	24
3 days	11.2%	28
Total		250

Statistics

Total Responses	250
Sum	528.0
Average	2.1
StdDev	0.3
Max	3.0

7. Where would you like future CPRIT conferences held?



Value	Percent	Count
Austin	39.3%	97
Dallas	16.6%	41
Houston	23.9%	59
San Antonio	18.2%	45
Other - Write In	2.0%	5
Total		247

Statistics

Total Responses	247

Responses "Other - Write In"	Count
Left Blank	247
Anywhere	1
Austin or Dallas	1
Dallas, Houston, San Antonio	1
Fort Worth	1
McAllen, TX	1

8. Please list topics/sessions you would like to see covered at future CPRIT conferences.

- - Immunotherapies - Targeted therapies - microRNA & ncRNA, lcRNA
- 1 disparities in cancer and health 2 use of big data for research questions 3 demography and health within cancer research
- 1) Small molecule therapies. 2) Workable strategies for \'basket\' trials and alternatives for patients not having actionable mutations.
- 1. Those with similar grants to have a breakout session to share wins and losses. 2. How to increase knowledge of evidence based practice with community physicians.
- 1. Cancer metabolism study 2. Computational works about the cancer study
- A look at progress and research in other disease sites such as pancreatic, etc. Maybe a session on survivorship as well.
- ACA issue/undocumented/access to treatment that is affordable
- Additional sessions regarding different types of projects.
- Administrative issues for grantees
- Advances in cancer therapeutics and new technology development.
- Advances in radiation/combined therapies Novel therapies/devices Advances in surgical management of cancer
- All good, need more
- Biostatics, Data analysis, comp sci, big data, and quantitative methods in cancer
- Bring policy makers to the panel. State representatives in public health committee. Involve them in conversation.
- Cancer and the problem/challenge of heterogeneity. Technology developments.
- Cancer biology
- Cancer diagnostics, novel methods and technologies with translational potential
- Cancer epigenetics
- Cancer Genomics and Genetics
- Cancer genomics, cancer biochemistry - breaking the groups down into how a group investigates cancer
- Cancer health disparities
- Cancer imaging for patients. There is progress in PET ligands and MRI methods. Texas has multiple high-end research imaging facilities and there is the opportunity, although a challenge, to have cross-campus collaborations to test some of these ideas.
- Cancer targeting small molecule treatment studies.
- Changes in breast and cervical cancer screening explained by a member of the US Preventive Task Force
- Childhood cancer
- Childhood cancer seems to be still far behind in terms of priorities for CPRIT funding/projects.
- Communication of CPRIT findings and work to the Texas population not just the legislature.
- Clinical or translational progress
- Cognition Radiomitigators Brain tumors / CNS tumors Treatment in CNS tumors
- Colorectal research, Dr. Katz.

- Community collaborators for programs Effective methods of program evaluation
- Community Health, Education,
- Companion Diagnostics plenary talk. Consider a formal \"speed dating\" session whereby CPRIT companies and potential CPRIT companies as well as other invested parties can interact in a structured way (e.g. 2-3 min per station, multiple stations in a session)..
- Computational biology and cancer modeling, Medical imaging
- Computational chemistry, computational surgery
- CPRIT grant administrations and policies
- CRIPSR/Cas9 topics in the plenary session
- Development of companion diagnostics in oncology, opportunities and challenges. This merits a keynote together with a panel discussion covering technical, clinical, regulatory, and commercial aspects.
- Developments in cancer therapeutics: what do we have so far?
- Diagnostics and instrumentation development
- Dissemination and Program Evaluation
- Drug discovery
- Efforts that address NCI's 12 provocative questions in cancer research.
- Environmental factors that influence cancer.
- Epigenetic and cancer
- Epigenetics and cancer
- Epigenetics hematologic malignancies
- Gene editing more on immune therapy and the clinical outcome product development research
- Glioblastoma and brain cancers. More academic research talks
- Health services research into new cancer treatments combination immunotherapies/biological therapies
- How CPRIT leadership and CPRIT grantees communicate our research progresses made because of the CPRIT funding
- How to work most effectively with primary care physicians
- I think it covered most subjects from basic science to clinical work.
- I think the topics covered were appropriate. More basic research would have been nice though.
- I would like more academic research updates.
- I would like to see more talks on basic and translational research.
- I would like to see sessions with introductions of key players in the drug development process - VCs, GMP facilities, animal facilities, etc. This should be immediately followed by networking or Q&A. Dr. Jung-Hee Woo (Baylor Scott & White) should be included as expert in GMP manufacturing.
- Imaging brainakevs, pathophysiology of tumors
- Immune therapies,
- Immunotherapy, cancer cell microenvironment, cancer stem cell
- Immunotherapy, pediatric cancer, brain tumors, personalized medicine, and single cell based research
- Improving access between academics and industry in Texas; Professional Development
- In addition to providing a source of funding for needed projects, CPRIT's role is more than that. It is the instigator and facilitator for bringing researchers and product developers together. It also has the ability to bring the academic centers together with the business community. 1. More formal networking opportunities that is akin to what is used at national conferences that allow the registrants to set up meetings in advance of the conference (like the B2B sessions at BIO) 2. Anatomy of a drug product from the bench to the patient. This should be a plenary panel discussion that helps researchers and developers see how a drug is developed and put into the market. 3. IP panel discussion - invention disclosures, patent filings, prosecution and protection. 4. More on university/biotech company collaborations and alliances and the related licensing, spin outs, earn in and buy ins. Also, how to navigate and consider the conflict of interest issues. 5. How to build a business plan and pitch a VC - the dos and don'ts.
- Inclusion of public health and community involvement opportunities and strategies
- Invite NIH speakers

- It was great to see environmental chemicals included on the program. I hope to see this again.
- Logistics of the application process, timelines for stages, etc. These would necessarily be broken up when not applicable for each category.
- Mechanisms of cancer non-coding RNAs and cancer
- Metabolomics
- Metallo drugs
- Metastasis
- Micro RNAs - targeted therapies
- Moe panels like the immunotherapy panel but on different hot topics
- Molecular aspects of prostate cancer and breast cancer How to educate the public about cancer risk factors How to design good experiments so they have a higher chance of entering clinical trials
- More academic research sessions, organized around the topics used to categorize the posters.
- More basic cancer research
- More basic science discovery and biotech development
- More colorectal cancer
- More conference-organized overview handouts on Texas specific small business and lab resources.
- More CPRIT Administration presentations to cover programmatic reporting, billing etc. for grantees. More education on prevention for cancer.
- More data (research) less industry
- More examples of successful products coming out of CPRIT support and how they got there. Since CPRIT only supports products/suppliers from TX, provide an area for booths where these companies can discuss what they provide to potential applicants or current grantees
- More from the realm of behavioral sciences pertaining to cancer prevention.
- More help on how to start company with CPRIT assistance
- More HPV
- More immuno-oncology and presentations by scientists about their research which collaborations they are interested in
- More lecture related to academia research cancer in prevention, diagnosis and therapy
- More mechanistic studies.
- More on breaking science --the immunology and prevention topics and speakers were so very timely and leading edge...so, more of this. I think a TED like session for one of the plenaries would be great.
- More on diet, exercise and lifestyle as CA prevention
- More on point of care diagnostics
- More on preventive services and how organizations are implementing grants
- More on translational research
- More prevention topics.
- More sessions on D&I/research
- More topic based presentations with panels to discuss state of the science and future directions. I really liked hearing about the liver cancer projects. Highlight prevention projects and the large funded projects and more discussion about statewide programs and involving DSHS
- Multi-Omic approach; Epidemiology; early detection of cancer
- N/A
- Nanomedicine
- Neuroscience/ brain behavior in cancer pediatric cancers (in comparison to adults)
- New techniques, new bioinformatics
- New therapeutics. Prevention Biology and implications to therapy
- NGS
- Non coding RNA TCGA data workshop
- Non-invasive imaging in clinical trials.
- Nuts and bolts product development workshop - cases histories
- Obesity prevention and management as an important step for cancer prevention
- Outreach Data collection Treatments
- Overview of all new Co's work funded by CPRIT and advancements to date

- Pain and management of pain associated with cancer and its treatment.
- Panel on guidelines for screening: breast and/or colorectal cancer
- Panels from Biotech companies supported by CPRIT discussing how CPRIT trainees (postdocs and/or PhD students) can apply for jobs in industry
- Pan-Omics discussion Functional Genomics - moving from research to the clinic
- Patient Testimonials Health Disparities nutrition Ethics/Research misconduct Emerging technologies Goals Round table discussion career development session for trainees Culture and belief in cancer prevention and treatment
- Pediatric cancer sessions - or interest sub group government/advocacy session and update from the state government
- Pediatric focused session(s) Sessions on screening in high risk groups
- Point of care instrument and clinical study.
- Poster meetings, more cross fertilization among similar projects in a structured manner
- Post-transcriptional regulation - a lot is heard about transcriptional regulation - but there were hardly any talks/posters on the role of RNA biology in cancer progression.
- Precision medicine
- Precision Medicine Immunology Biomarkers Environmental Exposures CPRIT Funded Grant Highlights
- Presentation of general areas that CPRIT grant awardees are working in. Ex: Liver Cancer - 2, Colon Cancer - 1, and Facilities Improvement - 4, Available Services Panel - Panel of Texas GMP manufacturers or other service providers that interact with CPRIT awardees.
- Prevention and early detection among immigrants (refugee, undocumented) Recent and dreamers - are in non-safety net systems.
- Prevention matters Breast/ cervical cancer guidelines need to change for prevention to continue.
- Prevention topics focused on nutrition, exercise, and lifestyle changes.
- Prevention track updates about current CPRIT projects
- Put dollars into open innovations and cover progress.
- Quarterly and Yearly Reports review
- Re-application process
- RNA therapeutics
- Single-cell analysis
- Small molecule approaches to cancer drug development. Immunotherapy and biologicals are \"hot\" right now, but new drugs entering the market are still mostly molecular. Such molecular systems are the backbone of current frontline therapy. Too little on this modality during the just-completed CPRIT Innovation Conference.
- Smoking / tobacco cessation and programs
- So you have your grant, now what...tips on effective awareness/prevention program building Common issues with prevention/research programs, how to combat them (based on past reports where barriers have been mentioned and the solutions to those barriers) Maybe have a session with survivors that can tell how research or specialized treatments has saved their lives and given them another lease on life. After all, these projects/grants/programs are to take a proactive approach to learning all we can about cancer and fighting to eradicate it. So why not hear for our heroes because what CPRIT does, affects every cancer patient worldwide, not just within Texas.
- Strategies in reading rural populations
- Success stories (if available) of what has made it from bench to bedside, or what has worked on the prevention side (cessation classes, etc.) if there's quantifiable data to support.
- Successful dissemination of CPRIT funded programs
- Sustainability approaches of community projects that are being conducted through grant funding
- Telomeres
- The increase in funding for prevention and screening programs from only 10% of the CPRIT budget to around 15 to 20%. There is so much more that we need to do across Texas and the availability to have more prevention and screening projects will benefit the whole state.
- The recent immunological breakthroughs line up well with Chinese traditional medicine which focuses on the immune system. Someone who could speak to this would be wonderful.

- The relationship between neurosciences and cancer, mind-body connections and their impact on cancer, etc.
- Theoretical progress on cancer
- Tobacco Cessation
- Update on Delivery System Reform Incentive Program (1115 waiver) and how it is impacting the delivery of preventive health in Texas.
- Working with Big Pharma NCI representatives and more national leverage

9. Who would you like to see as a keynote speaker at the next CPRIT conference?

- A public health official that could share is Texas doing better or worse as a result of the work that is being done.
- A speaker that will talk about advances in breast cancer.
- Advocacy group leaders
- Affordable Care Act expert - National and state
- Amelie Ramirez
- Andrew Conrad from Google. Surgeon General of the US
- Bob Weinberg
- Bob Weinberg Harold Varmus Michael Bishop
- Bring back David Katz
- Carl June
- Craig Thompson
- David Katz-9
- David Katz and Malcolm Brenner
- David Katz was an amazing speaker and I would be very interested in attending more of his presentations.
- David Rimm
- Dr. Brian Druker @ OHSC
- Dr. George Poste & Dr. David Katz
- Dr. Ness
- Dr. Robert Weinberg
- Dr. Roberto Villarreal with University Health System San Antonio, Texas
- Dr. Susan Love- Dr. Susan Love Research Foundation Julua Sweeney Mitchell Gaynor Mack Leon Dryden
- Dr. Susan Thooberry
- Drug Development/Pharma Exec Perspective on the industry and what we are doing in Texas. This could also be done with someone like Ron DePhino.
- Francis Collins or whoever is the head of NIH then (or whoever is head of NCI)
- From other states, such as MH, CA, etc.
- Further leaders in their respective fields of study such as Andy Futreal, David Sugarbaker, Anirban Maitra, and Ron DePinho.
- Garry Nolan, Stanford.
- Hard to beat this one. Mike White Trey Westbrook
- Harold Varmus
- Head of the FDA Oncology Division
- Jill Roark - CDC about HPV vaccinations
- Jim Allison
- Josh Menden
- Keep pounding the breakthroughs in thinking and approaches to cancer treatment
- Know particular speaker to recommend but it would be beneficial if there were separate speakers for the research grantees and the prevention grantees.
- Leaders in precision medicine
- Lewis Cantley, Charles Sawyer, Ralph Debernanidis (not sure of spelling UTSW Pediatrics and Genetics) George Poste keynote equivalent: John Condeelis, Albert Einstein (Big Data to Learn from Metastases
- Linda Birnbaum, NIEHS director
- Marc Sliwkowski (Genentech, CA)

- Mark Dewhirst - Duke/ Rene Gonzalez- UC Denver Med School
- Mark Muller, Carol Greider
- Mina Bissell (Breast Cancer Expert)
- More attention to cancer survivorship. Not survivor advocates, but innovations in research and care
- NCI directorate representative
- One of the Nobel Prize winners in Texas (such as one of them in UTSW)
- Pat O. Brown Philip Beachy
- President of the UT medical school to share vision of prevention in healthcare.
- Rama Ranganathan (UTSW) Jianpeng Ma (BCM) B. Montgomery Pettitt (UT Medical Branch at Galveston)
- Reps from NCI, Acs Uspstf cdc
- Robert Gropler.
- Robert Timmerman
- Robert Weinberg
- Robert Weinberg; Bert Vogelstein
- Ron DePinho
- Ron DePinho, Patrick Hwu of MDACC
- Secretary of Health and Human Services, Sylvia Mathews Burwell
- Sharon Dent
- Siddhartha Mukherjee see his TED talk Soon we'll cure diseases with a cell, not a pill
- Siddhartha Mukherjee, Author of The Emperor of All Maladies, A Biography of Cancer
- Some recognized name in cancer genomics, e.g. Bert Vogelstein
- Someone in tobacco cessation
- State policy makers or DHHS to hear how they plan to reduce cancer disparities
- Stephen Chanock
- Steve Lippard, MIT
- There are s0 many phenomenal researchers and contributors to impact cancer in Texas there's no way to select just one
- Theresa Beavers at MD Anderson
- Thomas Yankeelov (UT Austin), Sanjiv Gambhir (Stanford), John Gore (Vanderbilt)
- Tyler Jacks or Bill Kaelin
- Tyler Jacks, Arul Chinnayan
- Verry Shay
- Xiaolang Sunney Xie
- ZHIJIAN 'JAMES' CHEN The University of Texas Southwestern Medical Center STEVEN L. MCKNIGHT The University of Texas Southwestern Medical Center HUDA Y. ZOGHBI Baylor College of Medicine MARC SLIWKOWSKI Genentech, CA ERICK S. LANDER Broad Institute/MIT ERIC N. OLSON UT Southwestern Medical Center STEPHEN C. HARRISON Harvard Medical School

10. Other Comments/Suggestions:

Food

- Better lighting for the poster session room, some areas are a bit dark
- Breakfast at hotel was poorly organized. No buffet, understaffed, poor quality food/service
- Breakfast
- A little too broad for basic researchers. No breakfast?
- Don't run out of hot water for coffee break
- Healthier snacks would be nice!
- I hope CPRIT can provide breakfast and coffee in the morning before session getting started.
- Please, provide breakfast next conference
- Better food options. Overall enjoyed the conference.
- Very silly, but not having coffee to start the day was a little annoying.
- Why no breakfast!?
- Better coffee break organization; lines too long

- I hate to complain about the food, but the vegetarian options for lunch had no protein on Monday and very little on Tuesday (3 little pieces of tofu on salad) and was not really enough food for lunch.
- Room far too cold (Ballroom A) on day 1. Specifically say breakfast not offered. Beginning that early both days there is an expectation that breakfast is served. Serving a small salad for lunch on day 2 wasn't filling.
- Too many speakers went over time. Can timing be better stressed in future? Poor organization for coffee breaks and lack of healthy snack options
- Dinner and breakfast should be offered for the next meetings since it is a great opportunity for collaborations
- More coffee! Fresh fruit and yogurt rather than pastry. Save the paper! Nor more print out of poster abstracts....put them all on-line.
- On Tuesday conference lunch, there was not much for vegetarians for lunch. Just only the plate of salad was provided.
- I truly enjoyed the entire conference and am grateful to CPRIT for organizing the event however however the temperature in Ballroom was too cold most of the time even with a sweater. I would like coffee available early morning. The line for the coffee vendor was too long. Perhaps some healthy snack options would be good at break.
- Please provide breakfast first thing instead of food at break. Hotel was not friendly - didn't provide good service like late check out. I liked the 2 day format/schedule for Monday and Tuesday.
- The vegetarian lunch on day 2 was not at all sufficient. A small salad with three pieces of tofu and no dressing forced me to temporarily leave the conference to get something to eat. Coffee was not good.

Program Book

- Electronic programs and abstracts are better than the printed booklet
- Conference booklet in a searchable electronic form.
- Electronic copies of program materials would be better, with a page or two of updates at the meeting.
- The online / Mobile program should be more complete to include complete information about the sessions (i.e., room, session title, abstracts).
- The heavy booklet was too big and totally unnecessary. Next time save money and just send a pdf to all attendees. More drink options.

Conference Format/Logistics

- Having the conference during the week is not ideal.
- Annual frequency would be great
- Seating was very cramped and claustrophobic
- In the future, I think it is better not to end during the afternoon. I would suggest a half day-full day-half day format to get two full days.
- Extend full day into evening! Stay on time (Monday was poorly managed) Transition between sessions (poor in Ballroom from break to Maurer/Georgio session) Arrange with speakers to put presentations ideally in videos onto CPRIT websites Early morning coffee and healthy breakfast (re Katz) -- Okay to charge an extra $10-20 High throughput coffee breaks Longer Day 1, posters session with coffee, healthy food --One Session: Odds and Even - 60 minutes EACH --Coffee from 3-5 pm --Cash bar from 5-7 pm to encourage poster follow up and networking Use Day 2 for two minutes elevator talks of past 20-25 posters (Best 5%) I am disappointed that there are NO video recordings of this year's talks. PLEASE record the plenary and maybe all talks and post them on the CPRIT website, free access. For this year, collect slide decks from every speaker and post online. George McNamara - MD Anderson Cancer Center
- Choose a different hotel for the conference (poor planning, cola, poor service, bad food)
- Conference program was excellent Offer CE for professionals (nurses, physicians, etc.)
- Group B posters did not realize they could have posted their posters first thing; we all thought we were switching display boards with group A. Consolidate the poster sessions into one reception time. Explain to presenters that their posters should be posted early and throughout

the conference. You can still switch presenting (group A, B) during the consolidated time and put drinks/snacks in > 1 station throughout salon.
- Signs for different rooms/sessions. Breakfast could be served early, 8AM instead of the coffee break at 10.
- I would like to separate the conference into two major focus: 1. research & drug development/treatment 2. Prevention and early diagnosis alternate the two topics each year. Thanks very much.
- I chose 2 1/2 day conference because of flight connections. I don't live in a major metropolitan area and finishing so late in the afternoon meant I didn't get home till almost midnight. I didn't feel as though leaving early was a good option.
- I thought the conference was very good. I believe it would be better to have the conference for 1 1/2 days or 2 1/2 days so travel would be easier after the conference. Many people had to leave the conference early due to flights or long travel times home.
- The chairs were placed uncomfortably close together. The rows were too long, requiring individuals to practically crawl over other attendees to get to the empty seats in the middle. Also, the speakers did not adhere to the schedule
- CE for health professionals. I liked the fact that the hotel is isolated from the Austin night life, but the food at this hotel is not good and the food service is poor.
- Meetings should be at sites that most people can get to in one flight (without needing to make connections): likely Dallas or Houston. This would be a huge time savings and encourage participation.
- Lunch rooms in hotel freezing cold. Not a pleasant environment, though hotel was good. Poster sessions would benefit from more division of subject or keyword? They were not well attended, many people stood at posters with no people to look at them. How to get more attendees at poster sessions?
- in terms of supporting networking opportunities, most conferences offer long breaks between sessions to allow attendees to \"network\"; not sure you need 45 -60 minutes at the end of the 2nd day to achieve this...
  - I recommend to split the conference into three days. I like the format of the conference. There are many abstracts/poster presentations and because we did not receive the book until check in, it made it rather difficult to look over them. So instead, I found myself trying to go by all posters in hopes that the presenter would be there. In the future, I recommend a week or so before the conference to email out the abstract listing to the attendees. A few posters I stopped by, the presenter wasn't present. Although I can look up one of the authors (assuming one holds a faculty position or has a public profile), it would be nice in the future to put the email address of the presenting author in the conference book in the abstract section under the affiliations.
  - Negotiate free Wi-Fi in rooms, Eliminate $9 credit card registration fee, Keywords for abstracts, more abstracts available online
  - If going to have in a city, ACTUALLY have it in the city not 20 min north of the city in a hotel randomly placed in a mall. Have it downtown. IN THE ACTUAL CITY! VERY disappointing location in Austin.
  - I would prefer that the venue has Wi-Fi in the hotel rooms so that I could do work, write emails, and look up references online.
  - The AC is way too cold in the conference rooms. A mixer with cocktails one of the evenings would have been great.
  - This was the best CPRIT conference I have attended and I have attended them all. I like the Renaissance Hotel much better than the civic center; however, the ballroom was freezing.

<u>Content</u>
- Deeper research talks.
- Enjoyed the event and learn a lot. Thank you!
- GREAT CONFERENCE
- Great balance of different aspects of cancer research
- Great effort. Thank you
- I enjoyed the 2015 conference.
- I hope CPRIT will keep running. It benefits cancer research and all citizens in Texas.

- I would be nice to attend sessions based on specific projects.
- Include a track for administrators and those who manage these grants.
- It was a great experience! Thanks!
- It was good to see the limited staff achieving so much...
- More talks
- One of the best conferences put on by a granting agency I have ever attended.
- Poster sessions should be grouped by topics, i.e. HPV, Colorectal, Breast Health, Outreach, etc.
- Sessions about CPRIT application
- Thank you for a substantive, informative conference.
- There was little showing by CNS researchers
- I see a need for a smaller product development grant on the order of $50-250K. If done as a 25%-100% match on an SBIR or STTR award from the NCI it could really help get over the "valley of death" to prove the technology to be ready for a regular product development award. An added bonus is that the SBIR/STTR mechanism has anonymous reviewers, strong COI standards, is highly competitive, and found worthy of funding by the NCI or other NIH agency. If there were such awards, perhaps there could be a session of SBIR/STTR awardees with a match to highlight the benefits.
- I felt that the information presented during the poster sessions was great but was very disappointed at the number of posters left with no author involved in the work available for discussion.
- It was a wonderful experience being part of the conference. Would be a pleasure to have more possibility in future to contribute to it.
- Would be good to organize the poster abstracts by the days they are being presented, not all put together.
- This was my first CPRIT conference and I was truly impressed with all of the speakers and the commitment by all involved (from CPRIT and grantees) to improve the lives of Texans.
- Well done, good conference. Next time put the product development posters near the entrance of the presentation hall so there is more traffic and exposure.
- It would be great to have seminar titles on the printed program, even for the individual sessions. It would be great to upgrade the poster session so that more people attend.
- More time for posters and better clustering Breakfast with networking opportunities with tables labelled with topic areas so people can just gather
- Please, please, please insist that all participants keep their posters up until after the second poster session! I could view less than half my targeted posters since I presented in the first session and many were removed prematurely. This dramatically reduced the value of the conference for me, and stymied networking opportunities.
- Networking was very difficult. I wish CPRIT had organized optional evening Austin activities and had more structured networking opportunities. The poster sessions were difficult because half of the folks were presenting and snacks and drinks were so far from the posters. I would have liked to have online access to the poster abstracts ahead of time so I could plan. Conference might has also had better publicized Wi-Fi options.
- 1 Categorizing my "metabolomics" themed abstract into the existing categories was difficult. I saw metabolomics and proteomics posters mixed across very different categories and it would have been nice to clump them together. 2 It wasn't clear that posters supposed to stay up throughout the conference rather than taking them down after Session A ended, for example
- Issues in responding to item 6 - cannot click on responses for all. Pop-up blocker taken off and issue still unresolved. In Tuesday morning's Research Development panel session someone at the end of the session indicated they were compiling a list of Texas-based CRO's. Who was that person and will that be available through the CPRIT website so that we can reference it when preparing applications that require us to use Texas-based companies?
- First time attended. This is a very well organized conference with great information. Learned many great things and information.
- hairs were too close together in the ballroom A. Very uncomfortable having to sit touching shoulders with attendees on each side of you. Glass oaks room should have an aisle along the wall to the right as you walk in to make those seats more accessible. One other suggestion is give the authors of the best posters a chance to explain their posters. I have seen this done where they each get 5 - 6 minutes. Questions are then taken back at the actual poster during

the poster session. This could be done concurrently with the different poster categories: 1 hour, 12 posters, 3 rooms (depending on the number of rooms available) - 1. product development section 2 prevention section 3 academic session. Please put posters online in a searchable format. Do not provide the booklets unless they are requested. Provide recorded videos of the lectures after the conference, accessible to attendees.

- would like the conference to be more connected, with instance feedback and comments posted on a large social media display
- I wish were longer time allotments for the poster sessions. There were a lot to go through but with limited time.
- Meeting of Texas CRCS Coalition was a very important meeting, but it was held after conference hours and it would have been nice to see this worked into the schedule. These meetings would benefit all programs and similar gatherings could be held for each division at the same time instead of after hours. It would also be nice to have voice recordings made of the speakers and presentations so that we could go back and listen to breakout sessions we may have missed due to being in different sessions. These recordings would also be nice for the plenary session speakers. Just to be able to go back and re-listen to the important topic that were delivered very fast due to time constraints.
- Attendance and poster sessions were great. Access to coffee was hectic (long wait) Lunch buffet is more convenient than seating at the table a wait for service. At least one dinner (1st night) and all breakfasts should be offer by CPRIT
- Overall, the meeting was well-organized. The staff always seemed to know the answer to my questions, and were very nice.
- The poster sessions should have been on one day. There were far too many to see and half of the people at the conference only came for one day, so for those whose poster was on the second day, there was much less exposure.
- More opportunities for structured networking, separated by area of interest, would be helpful. I would also like to see more diversity in terms of having more women and minorities as speakers and panel members.
- The closing remarks where a little disappointing because I would have like to have heard more of a plan of "next steps/where are we going" as opposed to the panel discussion of what should be done. Some of the remarks seemed like it was a preaching to the choir discussion. Thank you for putting on a successful and informative conference. I enjoyed immensely.
- Very obviously a UT driven meeting with almost no panel representation from private schools. I liked the emphasis on product development, yet felt that the execution here was the biggest disappointment. It should also be standard to provide PDFs of the abstracts. It is impossible to skim all 500 abstracts for keywords ahead of the meeting.
- Most cancer presentations at this conference have benefited from CPRIT funding. A lot of current literature, including the findings from the President's panel point to obesity. I look forward to more funding directed to obesity prevention and management
- As an early career researcher, I was excited to have an opportunity to be in the presence of leaders and innovators in the cancer research and public health fields. However, outside of plenary and panel sessions, little time was available for networking between early and established investigators. In future events, I hope that more interactive opportunities are available and encouraged among attendees.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	PRODUCT DEVELOPMENT UPDATE
Date:	FEB 10, 2016

Summary and Recommendation

This memo provides an overview of Product Development activities since the last Oversight Committee meeting in November. Subjects include status of applications under review, membership changes for the Product Development Review Council, the business plan review process for Early Translational Research Awards, an update on my development of the Product Development Research program strategy, and a review on company-specific issues. The Product Development Research Program has no award recommendations to be considered at this meeting. However, I plan to seek approval for a change to a contract contingency the Oversight Committee approved in November.

Product Development Application Review Process Updates

Product Development Review Cycle 16.1

Five applications were recommended for due diligence reviews following the Product Development Research program panel reviews held in December. The business/regulatory due diligence and intellectual property reviews are expected to be complete in March for Product Development Review Council (PDRC) review and consideration. The PDRC's recommendations will be submitted to the PIC and Oversight Committee in May for approval. The total amount requested by the five applicants is $50.2 million.

Product Development Review Cycle 16.2

Requests for Texas Company and Company Relocation applications were posted to CPRIT's website in December. CPRIT's online portal is now open for application submission through February 28. The first review panel meetings will be held in early April to select the companies that will be invited for in-person presentations. Award recommendations from this cycle are expected to be considered by the Oversight Committee in August or September.

Product Development Review Council (PDRC) Membership

Dr. Kapil Dhingra, a PDRC member since 2010, is no longer able to participate with the PDRC due to other professional commitments. After discussion with the PDRC members, CPRIT has recruited two new PDRC members, Dr. Robert Sarisky and Dr. Neil Spector. Dr. Sarisky has a PhD and MBA and is currently Vice President of Business Development for Johnson & Johnson Pharmaceutical Services Oncology division. Dr. Neil Spector is an Associate Professor of Medicine at Duke University and the Co-Director of Experimental Therapeutics Program at the Duke Cancer Institute. Although they will be new to the PDRC, both Dr. Sarisky and Dr. Spector have been valuable members of the CPRIT Product Development Research review panels. Adding two members to the PDRC not only allows CPRIT to benefit from a wider scope of expertise but also increases the resources available to conduct progress and tranche reports.

Early Translational Research Awards (ETRA) – Business Plan Review

The Oversight Committee approved 20 ETRA grants to Texas academic institutions in November 2014. The objective of an ETRA grant is to "bridge the gap between promising new discoveries achieved in the research laboratory and commercial development." Consistent with that objective, one of the program requirements for these ETRA grantees is to submit business plans by March 31. The process of developing a business plan for the CPRIT project is intended to confirm that the principal investigator is taking appropriate steps toward developing a valid commercial opportunity for the CPRIT-funded technology. Product Development reviewers with business expertise will individually review the business plans and provide feedback to the ETRA grantees. The business plan requirement started with these ETRA grants and will be used again for the next round of ETRA grantees.

Company Connections and Other Activities

Since joining CPRIT late last year, I have met with 14 of CPRIT's active Product Development Research Program portfolio companies and several prospective applicant companies. I have also met with representatives of Johnson & Johnson's R&D incubator in Houston, The University of Texas MD Anderson Cancer Center, and the Texas Healthcare and Biosciences Institute (THBI), a Texas health sciences advocacy organization based in Austin. While getting a lay of the land in Texas, I am also identifying the best ways that the CPRIT's Product Development Research Program can support current and prospective portfolio companies and enhance connections with the Texas bioscience community, including technology transfer offices at Texas institutions. I am also assessing investment strategies and policies to optimize CPRIT's economic development and clinical impact within the parameters of the Oversight Committee's established program

priorities. I plan to briefly report on these projects at the February meeting. I am also scheduling individual meetings with all Oversight Committee members in the next few months.

Product Development Research Program Strategy

One of my first projects at CPRIT is to assess the state's cancer research and product development landscape and evaluate Texas' progress relative to other states. A key learning from this assessment is that compared to other states on a per capita basis, Texas falls behind in federal research funding, venture capital (VC) investment and startup efficiency. The investments CPRIT has made in the both academic and product development research have made a significant impact in Texas, but there is still work to be done to increase the state's life sciences infrastructure. I will discuss this assessment with the Product Development subcommittee and Oversight Committee members over the next few months.

I am currently working on an analysis of CPRIT's Product Development Research Program strategies and policies. The objective is to optimize CPRIT's clinical impact, while supporting efforts to grow the Texas life sciences community (see attached presentation). Preliminary suggestions include:

- Enhance collaboration with academic institutions to facilitate translation of research to commercialization. This will require the institution have strong interest in enhancing commercialization and appropriate internal culture and infrastructure;
- Support CPRIT grantees with early stage Product Development research projects that may not have external investors providing business oversight; and
- Focus Product Development research awards to early stage companies in proof-of-principle stage of development.

Equity Ownership Policy

Another early priority for me is developing a standard policy to manage our equity holdings. CPRIT currently holds equity in three companies: Cell Medica, Mirna Therapeutics, and Codiak BioSciences. (Codiak BioSciences is not a CPRIT-funded company; CPRIT's equity ownership results from the revenue sharing agreement with MD Anderson, who licensed work done by CPRIT recruit, Dr. Raghu Kalluri, to Codiak.) Both Cell Medica and Codiak are privately held, Mirna's equity is owned via publicly traded stock. The number of equity positions held by CPRIT may rise as our product development portfolio grows and an increasing number of CPRIT-funded companies engage in follow-on financings, acquisitions or other transactions.

CPRIT should establish a policy to manage equity ownership because it is efficient, transparent, and minimizes disruption to the CPRIT-funded company, which is particularly important when CPRIT owns a significant share of a company. For example, it may be advantageous that, as a

general policy, CPRIT hold shares of a private company until the company is acquired or is publically traded via an initial public offering (IPO). For publically traded stock owned by CPRIT, CPRIT may want to adopt a pre-scheduled stock sales policy. Pre-scheduling the stock sale and publicly announcing it provides transparency and avoids adversely impacting the market.

I will work with the Product Development subcommittee to devise and refine an equity ownership policy. The policy will need to be considered and approved by the Oversight Committee. An important part of this discussion is whether CPRIT is interested in taking equity in addition to/in place of CPRIT's royalty-based standard revenue sharing terms.

Company Specific Issues

- Kalon/Fujifilm Diosynth Biotechnologies
  Although CPRIT and Kalon executed the award contract in October 2014, the company has not yet drawn down any grant funds. Representatives from Fujifilm Diosynth, who now run the company after acquiring 49% of Kalon in a deal consummated in December, 2014, are still evaluating whether to continue the grant. One issue is the "change of control" option that CPRIT can exercise in its discretion if Fujifilm Diosynth acquires 50% or more of the company. Exercising the option requires Fujifilm Diosynth to repay any grant funds and terminates the contract. Fujifilm Diosynth has requested CPRIT waive the provision and is putting together a proposal for CPRIT's consideration.

- Peloton
  Kristen Doyle, CPRIT's general counsel, has provided you an update via a separate attorney-client privileged memo.

- DNAtrix
  DNAtrix recently reported good news regarding its work with the FDA and ongoing clinical studies. As a result, DNAtrix is seeking changes to its scope of work to reflect additional activities. I have discussed these changes with the PDRC and approved the expanded scope of work. However, in the course of working with company representatives, I have some questions regarding the company's established presence in Texas. CPRIT staff is following up with the company and will continue to monitor it.

- Ruga
  The Oversight Committee approved a $20 million investment in Ruga in November subject to three contingencies. The PDRC and I have reviewed these contingencies and believe have been successfully addressed. The Product Development subcommittee will

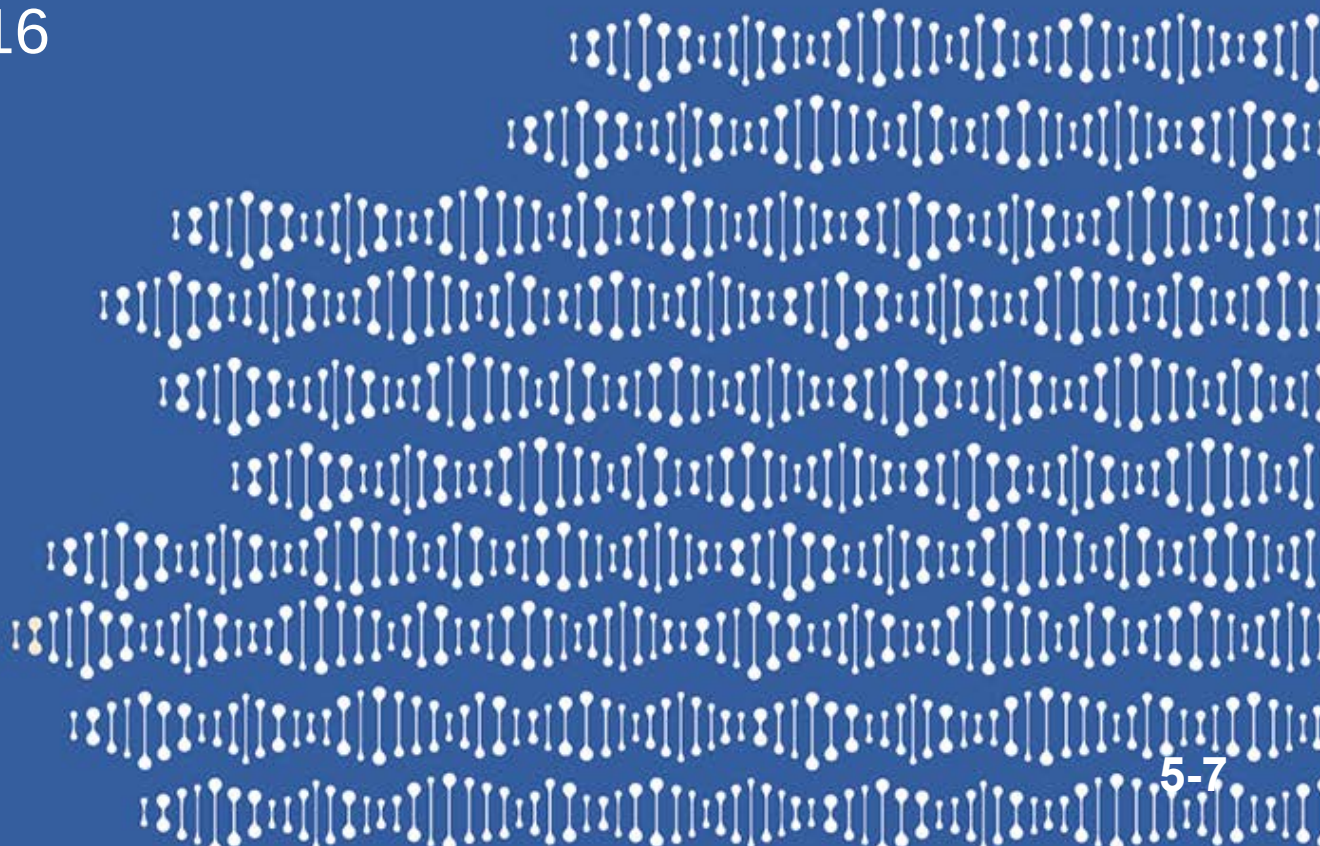
discuss the issue on February 11. A separate memo will be added to agenda packet requesting OC approval following the subcommittee meeting.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Texas Cancer Research & Development Landscape

February 17, 2016

Presented By:
Michael Lang



TX Health Care R&D Landscape

Contents

- TX Cancer Research and Development Landscape
- CPRIT Portfolio Overview

Cancer Research Funding – US & TX

NIH & NCI Research Grants	TX Research Grant Distribution
NIH Grants – Life Sciences Research • Total $22 B • Texas $980MM = 4.4% of US **NCI Grants – Cancer Research** • Total $2.9 B • Texas $204 MM = 7.0 % of US TX Pop 27 MM = 8.4% of US Pop or 9.4% of GDP	• UT system = 62% of TX NIH grants • Baylor College of Medicine = 14% of TX NIH grants • UT + BCM = 76% of TX NIH grants • MD Anderson = 50% of TX NCI grants

TX share of health care and cancer research are below our share of US population and GDP

Source NIH and NCI Websites Numbers are 5 year averages

VC Life Sciences Investment – US & TX

Total VC Investment	Life Science VC Investment
• $51 B Total VC Investments • $1.31B Total TX VC Investments • TX = 2.8% US VC investment	• $9.4B Total VC life sciences • $216MM TX VC life sciences • TX = 2.3% US VC investment **Distribution** • Average 14 Biotech investment / yr. • Average 13 Biotech investment / yr.

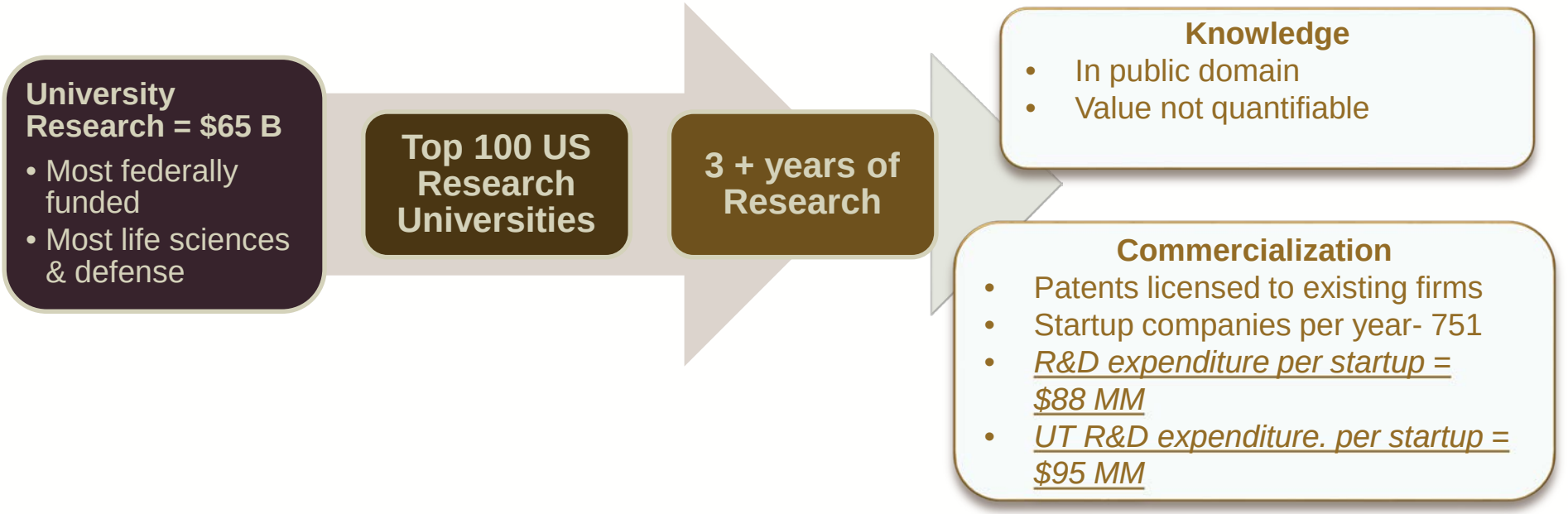
TX share of VC investment is below our share of US population and GDP.

CPRIT Impact on Cancer R&D in TX

NIH & NCI Grants to Institutions		VC Investment in TX
• Total NIH Grants	$24B	• TX VC investment into Health Care $216MM/yr.
• NIH- TX Research Grants Total	$970MM	• CPRIT Prod Dev Funding =$51MM
• NCI- TX Cancer Research Grants	$204MM	
• CPRIT Research Grants	$204MM	
CPRIT Doubles TX Cancer Research		CPRIT Increases TX VC Health Care VC Investment by 25%

CPRIT has significant impact.

US – University Research & Spinouts



Why is Research Spend per Startup so High?

- Funding supports both basic and applied science. Only applied science is commercially relevant.
- Research sometimes not aligned with clinical needs.
- University research not verified, sometimes can't be replicated.
- Limited commercialization focus and resources at University Tech Transfer Offices..

TX Life Sciences R&D Landscape

Contents

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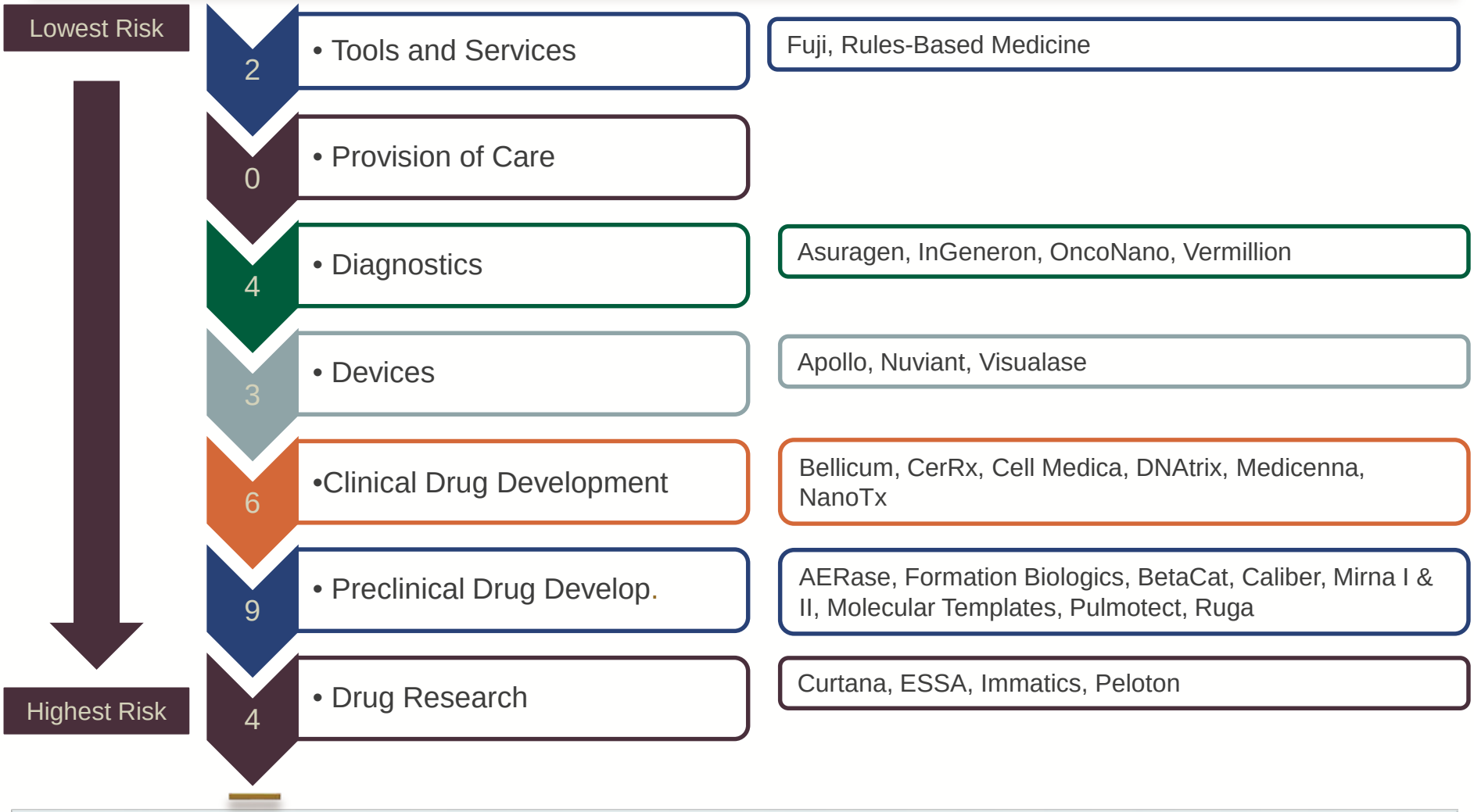
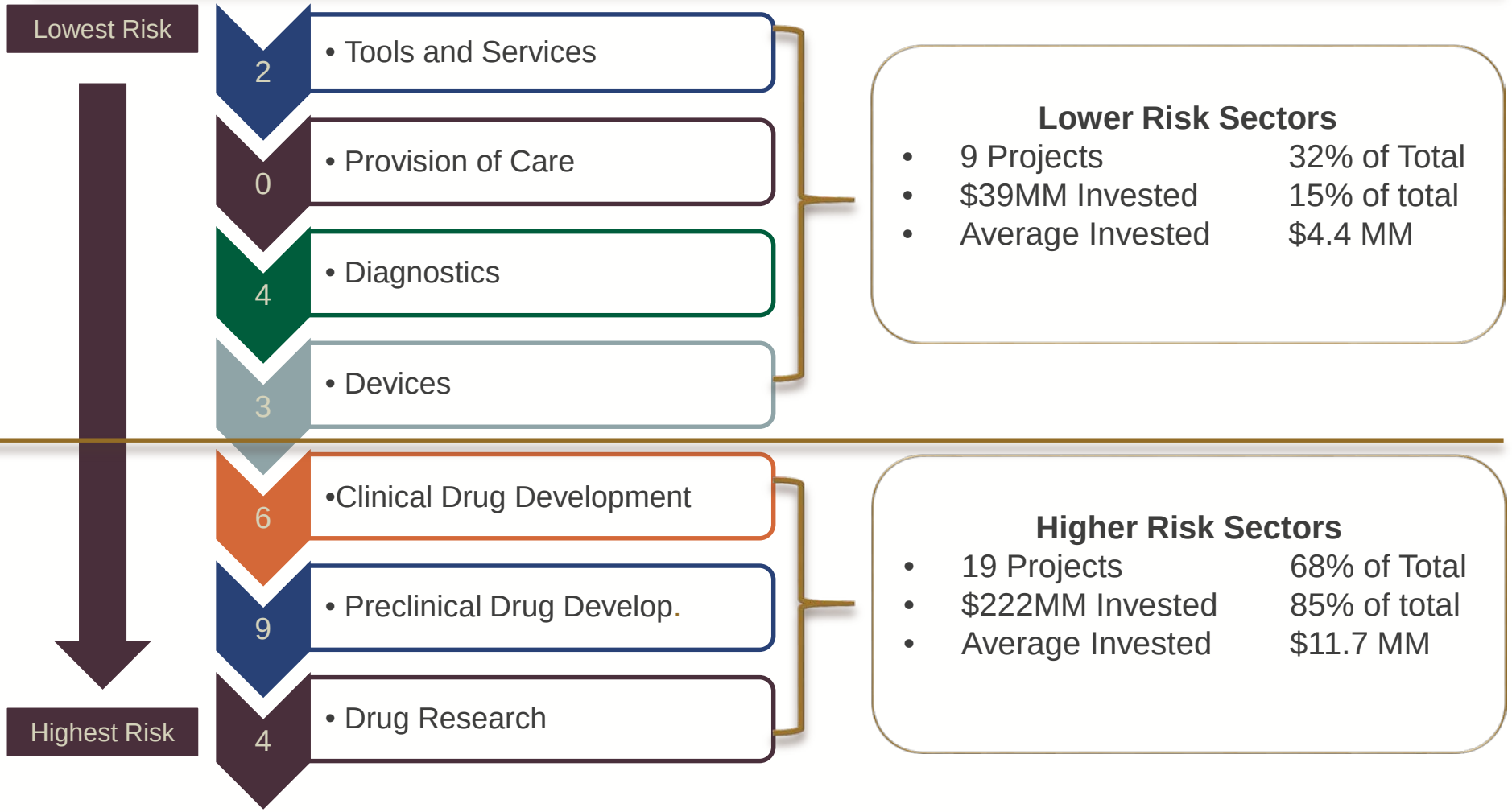
CPRIT Portfolio Overview



28 Investments; 19 in Oncology Drug Development (High Risk) & 9 in Other Sectors (Lower Risk)

CPRIT Portfolio Overview



CPRIT predominantly invested in oncology drug development.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE
From:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	DP150127 - RUGA CORPORATION CONTRACT
Date:	FEB 9, 2016

Summary and Recommendation

The Oversight Committee approved a $20 million grant award to Ruga at its November 19, 2015, Oversight Committee meeting. The Oversight Committee's approval was subject to three contingencies. Ruga has successfully addressed the contract contingencies. However, after reviewing company information, and conferring with representatives from Ruga and the Product Development Review Council (PDRC), it is my opinion that the requirement related to hiring a new CEO is no longer necessary.

I recommend the Oversight Committee delegate authority to CPRIT's Chief Executive Officer to execute the award contract with Ruga Corporation (Ruga) that does not include a contingency requiring Ruga to hire a new CEO. Ruga's contract and contingencies were discussed at the Feb 11 Product Development Subcommittee meeting. The Subcommittee concurs with my recommendation.

Discussion

Ruga has developed a novel drug to treat acute myelogenous leukemia, with some efficacy data in solid tumors. The drug candidate had demonstrated preclinical efficacy and limited preclinical safety data. The Oversight Committee awarded Ruga $20 million to complete pre-clinical toxicology and safety testing and Phase 1 clinical studies. The award decision was contingent upon the company adequately addressing three contract issues. Described below are the contract issues, the company's action to address the issues, and my opinion regarding whether the company has sufficiently addressed the issues:

1. Renegotiate the license with Stanford. The concern was that the return to Stanford was too high at 15% and may dissuade follow-on investment.

After discussions with company representatives and a detailed analysis of the license agreement, I am satisfied that the 15% royalty rate is applicable only in the event that Ruga sublicenses the technology. If Ruga were to sublicense the patents after receiving IND approval, the company would pay Stanford 15% of the sublicense fee they receive. If the license occurred later in the development process, the rate drops. These terms are typical of drug industry licensing and likely would not be an impediment to future financing.

With the exception of this narrow circumstance, revenue royalties paid to Stanford vary between 1% and 3%. These rates are at or below industry standard, hence attractive for Ruga. The IP diligence report does not note concerns related to royalty rates or other payments.

The PDRC and I both recommend that this contingency be considered fully addressed.

2. Confirm that Fujifilm Diosynth, Ruga's planned contract manufacturer, does not require additional royalty payments via the manufacturing agreement.

   Ruga agrees with this concern. The company is negotiating with Fujifilm Diosynth to reduce cost and confirm that no royalty is applicable because of the manufacturing agreement. Ruga has received quotes from other contract manufacturers that also meet their needs at comparable costs with no royalty requirements. If Fujifilm Diosynth requires royalty payments as part of the manufacturing agreement, then Ruga is prepared to utilize alternative vendors.

   The PDRC and I recommend that this contingency be considered sufficiently addressed for the purpose of executing the contract. Ruga will update CPRIT on the selection of a contract manufacturer.

3. Confirm plans for Texas relocation and Ruga staff changes. This contingency has four parts:

   - Ruga establishes its headquarters and operations in Texas. The company confirms that the CEO and other C-level staff will be based in Houston at Texas Medical Center. CPRIT will monitor this requirement as part of our standard compliance program.

- A full time outward-facing CEO be in place. Ruga has a full time CEO, Dr. Ray Tabibizar, with the appropriate industry and medical background. Dr. Tabibizar was a practicing cardiologist who has worked in Pharma industry since 2003. His experience includes Vice President of Translational Research, Chief Scientific Officer and venture capital roles.

- Hire a Chief Medical Officer (CMO), Director of Manufacturing, Vice President of Clinical and Regulatory Affairs, and a Program Manager. Ruga plans to recruit at least two executives to the company; a Chief Development Officer (CDO) and a CMO, upon closing with a third person hired soon after. They report; "we are currently in discussions with one candidate for the CDO role and two candidates for the CMO role. All three have extensive background both in small and large pharma company." The company plans to enter into definitive negotiations with these individuals to secure the positions Ruga also plans to retain the services of the technology developer from Stanford on a 50% basis.

- Engage consultants with specialized expertise in chemistry, manufacturing, and controls (CMC) for fusion proteins, preclinical, and regulatory affairs within the first year of award. The company recognizes this need and is in discussion with several firms with recognized expertise in these areas.

CPRIT's PDRC and I both recommend CPRIT consider all issues under the third contingency addressed for purposes of executing the contract. The issue requiring Ruga to hire a full-time, outward facing CEO appears to contemplate that Ruga recruit a new person to the company to fulfill this role. The PDRC originally requested this contingency. However, in a follow up discussion with the PDRC, it appears that the PDRC was operating under a misunderstanding that Ruga's Chief Scientific Officer, Dr. Amato Giaccia, was also serving as the company's CEO. Dr. Ray Tabibiazar is the company's CEO. As noted above, Dr. Tabibiazar has experience that includes Vice President of Translational Research, Chief Scientific Officer, and venture capital roles. The PDRC and I agree that Dr. Tabibiazar has the appropriate industry experience and medical background for the CEO role at Ruga. For these reasons, we recommend that the requirement that Ruga hire a new CEO is unnecessary.

Recommendation:

Ruga has successfully addressed the contract contingencies approved at the November 19, 2015, meeting. I recommend that the Oversight Committee delegate authority to CPRIT's Chief

Executive Officer to execute the award contract with Ruga Corporation (Ruga). The delegation of authority should not include a requirement compelling Ruga to hire a new CEO. I presented this information and my recommendation to the Product Development Subcommittee on February 11. The Subcommittee concurs with my recommendation.

Dr. Karen Patricia Williams is the Nursing Distinguished Professor of Women's Health and Director of the Center for Women, Children & Youth, College of Nursing at The Ohio State University. Her previous position was as a Professor with the Department of Obstetrics, Gynecology and Reproductive Biology at Michigan State University College of Human Medicine. Her expertise is in community-based research and health services research with medically underserved women. She received her BA degree in Journalism; her MA degree in Adult and Continuing Education/Higher Education Administration, and her PhD in Community Development. Her transdisciplinary education has provided her with a unique perspective that has informed her research.

RESEARCH:
The complexity of the phenomena of health disparities requires researchers and public health educators to use many strategies to devise ways of reducing disparities and implement programs with the goal of eliminating those disparities. Research conducted under the direction of Dr. Williams includes design, testing and implementation of a multigenerational life span breast and cervical cancer prevention and screening intervention, focused on Black, Latina and Arab women; The Kin KeeperSM Cancer Prevention Intervention. This work is bringing knowledge to bear on cancer prevention and control by: 1) contributing to the theories that link community, provider and family to behavioral outcomes for medically underserved women; 2) testing and implementing the model to demonstrate its adaptability to other underserved populations; 3) promoting cancer prevention/screening practices across the life span of women through a multigenerational model; and 4) expanding the use of existing resources by building on established programs, such as maternal/prenatal care programs.

AREAS OF EXPERTISE:
Breast cancer, cardiovascular disease, community outreach, health disparities, minority health, women's health

CURRICULUM VITAE

KAREN PATRICIA WILLIAMS, Ph.D.

ADDRESS

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Ohio State University
College of Nursing
Center for Women, Children & Youth
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East Lansing, MI 48824-1316

[redacted]

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www.kinkeepermodel.org

EDUCATION

Ph. D. 1998 Michigan State University
Major: Community Development, with emphasis in Community-based Health Programs

Dissertation Topic: *An Analysis of Community Development Approaches to Cardiovascular Disease Prevention Projects for African Americans*

M. A. 1993 Michigan State University
Major: Higher Education Administration, with emphasis in Adult and Continuing Education

B. A. 1984 Temple University
Major: Journalism, with emphasis in Print Media

Research Interests: Cancer prevention and control for underserved women; Community-based interventions focusing on underserved women; Health services research; Cancer disparities.

HONORS

2015, National Institute of Nursing Research Story of Discovery
2015, American Cancer Society, Spokesperson
2015, Co-Chair, March of Dimes, Signature Chef Fund Raiser
2013/2014 Fellow, Executive Leadership in Academic Medicine, the International Executive Leadership in Academic Medicine Program at Drexel University
2013 Fellow, American Association for Cancer Education
2012/2013 Fellow, Academic Leadership, Committee on Institutional Cooperation (CIC)
2012 President, American Association for Cancer Education
2011 Chair, Health and Human Services, Central Area, The Links, Incorporated
2011 Received Michigan Cancer Consortium Spirit of Collaboration Award
2009 Vice President, American Association for Cancer Education

2008 The R. Davilene Carter Presidential Award for Best Paper Submitted, American Association for Cancer Education
2008 Scientific Membership in the Karmanos Cancer Institute, a National Cancer Institute Comprehensive Cancer Center, Population Studies and Prevention Research Program
2004 National Cancer Institute Principles and Practice of Cancer Prevention and Control Course Participant
2003 Governor's Appointment to Michigan Women's Commission
2003 Diana Award, YWCA of Greater Lansing
1999 Health Services Fellow, American Association of Medical Colleges
1992 Kappa Delta Pi, Education Honor Society

PROFESSIONAL EXPERIENCE

January 2016-Present **Nursing Distinguished Professor of Women's Health**
Director, Center for Women, Children & Youth, College of Nursing, Ohio State University, Columbus, OH. This primary Center in the College is comprised of more than 20 clinical and research faculty who engage in the discovery of new knowledge and its translation into real world settings to optimize health and wellness outcomes in infants, children, adolescents and women through health promotion and risk reduction.

June 2015 – Present **Professor w/tenure,** Department of Obstetrics, Gynecology & Reproductive Biology, College of Human Medicine, Michigan State University, East Lansing, MI
Research: Principal Investigator on four National of Institutes of Health funded R21 -- Linking Education to Action: A Program to Increase Research Participation; completed R01 – Kin Keeper^{SM}: Reducing Cancer Disparities through Cancer Literacy and Screening – completed NIH R21 project and NIH Diversity Supplement as well as 15 closed projects. Manage and support a research team of four people at Michigan State University. Currently I am collaborating with the Mayo clinic and an African American women's organization to understand biomedical research participation among African American women. Most recently, I have expanded the utility of the Kin Keeper^{SM} model to implement it within a Federally Qualified Clinic, the NIH application is under review. I have collaborated with community-based partners in southeast Michigan: Detroit – Department of Health & Wellness Promotion Latino Family Services; Dearborn – Arab Community Center for Economic and Social Services.

July 2010 – Present **Associate Professor w/tenure,** Department of Obstetrics, Gynecology & Reproductive Biology, College of Human Medicine, Michigan State University, East Lansing, MI
Research: Principal Investigator on two National of Institutes funded R01 projects – Kin Keeper^{SM}: Reducing Cancer Disparities through Cancer Literacy and Screening – completed NIH R21 project as well as 15 closed projects. Manage and support a research team of four people at Michigan State University. Collaborated with community-based partners in southeast Michigan: Detroit – Department of Health & Wellness Promotion Latino Family Services; Dearborn – Arab Community Center for Economic and Social Services.
Service: Michigan State University Women's Advisory Committee to the Provost; College of Human Medicine Diversity & Inclusion Task Force; Scholarship

Committee; Department Executive Committee; National Institutes of Health Center for Scientific Review Charter Study Section; Editorial Board, Associate Editor, Journal of Cancer Education; Priority Health, Quality Integration Committee, The Links Incorporated – Health and Human Services Committee.
Teaching: Teach three undergraduate medical school courses: Clinical Skills III – HM 534, Medical Humanities – HM 548, Human Development – HM 543. Teach one two-semester research seminar for MSU Honors College: H-014. Train community health workers' using: Kin Keeper℠ Cancer Prevention Intervention Curriculum Guide and Workbook© 2007. Developed a web site, www.kinkeepermodel.org. Developed a training manual for dissemination, The Kin Keeper℠ Training the Trainer Manual, copyright pending.

Jan 2004 – 2010 (Tenure System)

Assistant Professor, Department of Obstetrics, Gynecology & Reproductive Biology, College of Human Medicine, Michigan State University, East Lansing, MI
Research: Principal Investigator on two active externally funded projects – (1) Health Disparities: Survey Validation for Black, Latina and Arab Women; (2) Examining Trust and Cancer Literacy on Breast Cancer Screening – and 14 closed projects. Manage and support a research team of four people at Michigan State University. Collaborate with three community-based partners in southeast Michigan: Detroit – Department of Health and Wellness Promotion Village Health Workers program; Community Health and Social Services Center, REACH; Dearborn – Arab Community Center for Economic and Social Services.
Teaching: Teach three undergraduate medical school courses: Clinical Skills III – HM 534, Medical Humanities – HM 548, Human Development – HM 543. Teach one two-semester research seminar for MSU Honors College: H-014. Designed curriculum for community health workers' training: Kin Keeper℠ Cancer Prevention Intervention Curriculum Guide and Workbook© 2007. Developed a curriculum to support a community health worker institute; NIH/NCI proposal is under review.
Service: College of Human Medicine Scholarship Committee; National Institutes of Health ZRG1HOP-U (91) S Review Committee; Editorial Board, Associate Editor, Journal of Cancer Education.

June 2002 – Jan 2005 **Diversity Officer**, Office of the Dean, College of Human Medicine, Michigan State University, East Lansing, MI
Responsible for monitoring Affirmative Action and Compliance for the College. Chair of the College Diversity Committee. Served as the College's representative on the University's Affirmative Action and Compliance committee.

Nov 1998 – Dec 2004 (Annual Appointment System)

Assistant Professor, Department of Obstetrics, Gynecology & Reproductive Biology, College of Human Medicine, Michigan State University, East Lansing, MI
Teaching: Medical Humanities and Human Development and Behavior. Provided insight into the relationship between women's health issues, community health and minority health issues with impact on women's health. Worked on departmental research projects involving infant mortality review and infant mortality reduction and identification and prevention of domestic violence, especially during pregnancy. *Research*: Women and complementary and alternative medicine; testing a female-focused community-based health advocacy

model; women's health policy in Michigan; African American women and cardiovascular disease; and the best methods to reach low-income women regarding their health.

May 1994-2002 **Coordinator,** Center of Excellence in Minority Education and Health, College of Human Medicine, Michigan State University, East Lansing, MI
Coordinated a federally funded program with an annual budget of $5 million, which addresses minority health research, medical school recruitment and retention. Assisted in preparation for federal site visits. Developed and presented program budgets. Contributed significantly in preparing the federal progress report. Responsible for the implementation of the newly formed information resource center, an electronic database. It links students, faculty and researchers to current publications, research and other resources in the area of minority health that are necessary to promote curriculum development and research. Designed and implemented a non-academic retention model for medical students of color that connects first-, second-, and third-year medical students with seasoned physicians within Ingham County. Responsible for developing a statewide minority premedical student network for use in recruitment. Organized statewide minority premedical conferences. Responsible for the College of Human Medicine's MCAT Review Program. This program supplies students with strategies for success on the medical entrance examination. Developed and implemented a summer research program for medical students. Selected and managed the personnel who administered the program. Managed a staff of six professionals and two Para-professionals. Organized the medical school's first statewide health conference for women of color, using a community collaborative model. Interacted with local media, other units on campus and community groups to promote COE programs and projects. Represented the College on the statewide Year of the Women's Health Initiative Steering Committee.

Sept 1996-2004 **Consultant,** Michigan Public Health Institute, Okemos, MI
Served as a consultant to the Resource Center for Cardiovascular Health to evaluate and conduct research on statewide cardiovascular disease prevention programs for African Americans. The project is still in progress.

Aug 1994 – May 1995 **Career Coordinator**, College of Agriculture & Natural Resources, Resource Development Department, Michigan State University, East Lansing, MI
Advised, informed and assisted undergraduate students, graduate students and alumni in career planning and job placement. Developed relationships with employers through on-site visits and telephone interviews. Contacted potential employers regarding employment for undergraduate and graduate students. Worked with Michigan State University Career Development and Placement Services to coordinate services offered to students. Designed and implemented workshops that fostered professional development for students and linked them to the world of work.

Jan 1995 – May 1995 **Presidential Intern,** Office of the President, Lansing Community College, Lansing, MI
Shadowed the president of Lansing Community College to gain first-hand knowledge of the administrative responsibilities and to observe the leadership qualities necessary to manage a college. Attended cabinet, budget, staff and board meetings. Conferred with the president weekly.

Aug 1993 – May 1994 **Teaching Assistant,** College of Agriculture & Natural Resources, Resource Development, Michigan State University, East Lansing, MI
Maintained records, designed case studies for two courses: Resource Management and Planning and Environmental and Natural Resources. Responsible for designing the senior service-learning project for the department. Students were given the opportunity to design a sustainable urban environmental curriculum for an elementary school in Detroit. Teachers use the lesson plans to enhance the science skills of the young students. Contributed significantly to a departmental funding proposal.

Aug 1992 – Aug 1993 **Assistant Coordinator,** Summer University Program Encouraging Retention (SUPER), Office of Supportive Services, Michigan State University, East Lansing, MI
Designed and evaluated an academic summer preparation program for minority first-year students who were entering the university that fall. The seven-week program included college level courses and enrichment programs to help students make a successful transition in the fall. Worked with various colleges and units on campus, such as the Office of the Provost, Admissions and Financial Aid, and school districts across the state. Developed a career/leadership workshop that utilized community leaders from different fields. Designed a brochure and managed the marketing packet that was mailed to high school seniors.

Oct 1989 – June 1993 **Assistant Director,** School Nutrition Services, ARA Service, Jackson, MI
Administered a $1.5 million budget and oversaw the day-to-day operations of a K-12 school system's nutrition department. Responsibilities included forecasting budgets, negotiating contracts, building a customer base by creative marketing, and ensuring compliance with all state and federal regulations. I also interviewed, selected, trained, counseled and managed a staff of 65 skilled workers and Para-professionals; coordinated staff development; and designed age-appropriate nutrition programs.

Oct 1987 – Sept 1994 **College Instructor,** Prison Program, Jackson Community College, Jackson, MI
Prepared and taught two English courses: Business Communications and Speech Communications. Edited a training manual for incoming instructors.

Oct 1986 – Mar 1987 **Legislative Aide,** Michigan State Senator Jackie Vaughn, III, Lansing, MI
Served as the senator's assistant in solving problems arising from his work on the Appropriations, Corrections, and Community Colleges and Higher Education Committees. Analyzed and resolved constituent problems; worked with the state agencies in referring problems.

Jan 1984 – Aug 1985 **Reporter,** *Jackson Citizen Patriot*, Jackson MI
Covered five school districts, six townships, and the African American Community. Wrote the newspaper's first series on the history of African Americans in Jackson. Designed a countywide program to promote readership during Black History Month.

TEACHING EXPERIENCE

Clinical Skills, Human Development and Behavior, Medical Humanities 14 years (Second-Year Medical Students)

Women in Medicine, seven years (First Year Medical Students)
Minority Health Summer Research Experience Seminar (First and Second-Year Medical Students)
Honors Research Seminar – two years (undergraduate students)
Business Communications, seven years (Community College Students)
Speech Communications, seven years (Community College Students)
Breast and Cervical Cancer Prevention and Control Basics – nine years (community health workers)

STUDENT ADVISING/MENTORING

Undergraduate Advisor for 30 Premedical Students
Independent Study for Undergraduates
- Gina Brooks
- Shamia Isaac
- Alisha McCon
- Aisha Henderson
- Shimaa Mousa
- Brandon Bishop
- Desirae Smith (Langston University)
- LeStella Bell
- Jamila Edwards

Ronald E. McNair Post-Baccalaureate Achievement Program Mentor
- Jene Moy
- Lona Vincent (Hampton University)
- Sandte Stanley

Mentor/Research Supervisor for Graduate Students
- Waseya Cornel, Second-Year Medical Student/Doctoral Student
- Faith E. Fletcher, Bioethics, Master's Candidate
- Resche Hines, Education Doctoral Student
- Jonghwan Lee, Doctoral Student
- Jonathan Livingston, Community Psychology, Doctoral Candidate
- Ta-Tanisha Manson, Law Student
- Nana Mireku, First-/Second-/Third-Year Medical Student
- Vaishali Patgaonkar, Political Science, Master's Candidate
- Ola Rostant, Education Doctoral Student
- Eric Powell, Undergraduate Premedical Years and First-/Second-Year Medical Student
- Rebecca Torres, First-Year Medical Student
- Patricia Shropshire, Sociology, Doctoral Candidate
- Kimara Wisenant, First-/Second-Year Medical Student
- Omara Rivera-Vazquez, Doctoral Candidate
- Athur Mabiso, Agricultural Economics Doctoral Candidate
- Julie Williams, Third-Year Medical Student
- Alisan Fathaizadeh, Third-Year Medical Student
- Samia Arshad, University of Michigan Public Health Student
- Ezinne Ndukwe, University of Michigan Public Health Student

Graduate Committees
- Margaret Dimond, Social Work, Doctoral Candidate
- Faith E. Fletcher, Bioethics, Master's Candidate

Resche Hines, Education Doctoral Candidate
Samantha Nazione, Communications Doctoral Candidate
Tenisha S. However, History Doctoral Candidate

FUNDED RESEARCH

1. Michigan State University Honors College
Source: Federal Government
Title: Conducting Community Based Research while Applying Informatics
Position: Principal Investigator ($5272)
September 2015-April 2016

2. National Institutes of Health
Source: National Cancer Institute (1R21CA191028-01)
Title: Linking Education to Action: A Program to Increase Research Participation
Position: M-Principal Investigator ($275,000)
September 2014 – August 2016

3. National Institutes of Health
Source: National Institute of Nursing Research (1R01NR011323004S1) Diversity Supplement
Title: Kin Keeper[SM] Reducing Disparities through Cancer Literacy and Screening
Position: Principal Investigator ($24,312)
July 2013- June 2015

4. National Institutes of Health
Source: National Institute of Nursing Research (1R01NR011323)
Title: Kin Keeper[SM] Reducing Disparities through Cancer Literacy and Screening
Position: Principal Investigator ($2,243,890)
September 2010- June 2015

5. National Institutes of Health
Source: National Institute of Nursing Research (1R21NR010366)
Title: Reducing Health Disparities: Survey Validation for Black, Latina and Arab Women
Position: Principal Investigator ($238,645)
December 2008-November 2011

6. National Institutes of Health
Source: National Institute on Aging
Title: Michigan Center for Urban African American Aging Research
Position: Junior Investigator ($19,555)
July 2008-June 2009

7. Susan G. Komen for the Cure
Source: National Foundation (Dallas, TX)
Title: Examining Trust and Cancer Literacy on Breast Cancer Screening
Position: Principal Investigator ($297,995)
May 2007-April 2009

8. Michigan State University Honors College
Source: Federal Government

Title: Conducting Community Based Research for Medically Underserved Women
Position: Principal Investigator ($6,800 each year)
September 2007-April 2008
September 2008-April 2009

9. Michigan Dept. of Community Health
Source: Federal Government
Title: Kin Keeper[SM] Cancer Prevention Intervention
Position: Principal Investigator ($296,267)
October 2006-2008

10. Susan G. Komen for the Cure Greater Lansing Affiliate
Source: Local Foundation
Title: Expanding Cancer Prevention through Translation and Training
Position: Principal Investigator ($32,000)
June 2006-May 2007

11. Susan G. Komen for the Cure
Source: National Foundation (Dallas, TX)
Title: Testing a Family Breast Cancer Prevention Intervention
Position: Principal Investigator ($249,991)
May 2006-April 2008

12. Michigan Department of Community Health
Source: Federal Government
Title: Kin Keeper[SM] Cancer Prevention Intervention
Position: Principal Investigator ($242,638)
October 2005-September 2006

13. Susan G. Komen for the Cure Greater Lansing Affiliate
Source: Local Foundation
Title: The Kin Keeper[SM] Project Linking with African American Women for Breast Health and Wellness
Position: Principal Investigator ($20,000)
June 2003-May 2004

14. African American Family Initiative
Source: Michigan State University
Title: Kin Keeper[SM]: A Conceptual Model for Cancer Prevention and Screening Intervention in African American Women
Position: Principal Investigator ($2,000)
June 2003-August 2003

15. African American Health Initiative
Source: Michigan State University
Title: African American Women's Knowledge, Beliefs and Willingness to Participate in a Preventive Breast Cancer Clinical Trial
Position: Principal Investigator ($20,000)
January 2003-December 2003

16. National Cancer Institute

Source: Federal Government
Title: Minority Supplement to the National Surgical Adjuvant Breast Bowel Project
Position: Minority Investigator ($290,166)
February 2002-January 2006

17. Michigan Applied Public Policy Funds
Source: State Government
Title: Women's Health Policy in Michigan 1997-2000
Position: Principal Investigator ($25,000)
May 2001-December 2001

18. W.K. Kellogg Foundation
Source: National Foundation
Title: Michigan Forum of Scholars of Color: The Development of Community and Faculty Partnerships to Improve the Health of Communities
Position: Principal Investigator ($58,959)
June 2000-December 2001

19. American Association of Medical Colleges (Health Services Research Fellowship)
Source: Federal Government
Title: Complementary and Alternative Medical Usage Patterns Among Middle-Aged Black and White Women with Female Cancers and Cardiovascular Disease (proposed concept)
Position: Fellow ($3,000)
August 1999-March 2001

20. Michigan State University Cancer Center
Source: Federal Government
Title: Healthy African American Women's Perspective on the Use of Complementary and Alternative Medicine for Cancer Treatment and Prevention: A Pilot Study
Position: Principal Investigator ($1,000)
September 1999-December 1999

Under Review/Pending
1. National Institutes of Health
Source: National Cancer Institute
Title: Kin Keeper[SM] from Community to Clinic Next Generation Implementation
Position: Principal Investigator

PUBLICATIONS

Peer-Reviewed Manuscripts (*denotes senior/corresponding author)

1 . **Williams, K.P.** Ford, S., Meghea, C.I.. Cultural Connections: the Key to Retention of Black, Latina and Arab Women in the Kin Keeper[SM] Cancer Prevention Intervention Studies. Journal of Cancer Education On-Line July 2015

*2. Talley, C. H. & **Williams, K. P.** Impact of age and comorbidity on cervical and breast cancer literacy of African American, Latina, and Arab women. Invited Special Issue- Rural and other underserved Medically Underserved Populations. Nursing Clinics of North America. September 2015.

3. **Williams, K.P.,** Talley, C. Smith, D. Cervical Cancer Awareness among Black, Latina and Arab Women. Journal of Black Nurses' Association. 25(2): 31-38. 2014 .
4. Adams, I., Christopher, J., **Williams, K.P.,** Sheppard, V.B. What Black Women Know and Want to Know About Counseling and Testing for BRCA 1/2. Journal of Cancer Education. In Press
*5. Zambrana, R., Meghea, C., Talley, C.H., Hammad, A., Lockett, M. **Williams, K.P**. Association between Family Communication and Cancer Health Literacy among Underserved Racial Ethnic Women. Journal of Health Care for the Poor and Underserved. 26: 391-405, 2015.
6. Sheppard, V.B., **Williams, K.P.**, Wang, J., Shavers, V., Mandelblatt, J. An Examination of Factors Associated with Healthcare Discrimination in Latina Immigrants: the Role of Healthcare Relationships and Language. Journal of National Medical Association 106(1): 14-21, 2014
7. Meghea, C., **Williams, K.P.** Aligning Cost Assessment with Community-Based Participatory Research: The Kin Keeper[SM] Intervention. Journal of Health Education Research. Online November 2014.
8. Sheppard, V.B., Graves, K.D., Christopher, J., Hurado-deMendoza, A., Talley C., **Williams, K.P.** African American Women's Limited Knowledge and Experiences with Genetic Counseling for Hereditary Breast Cancer. Journal of Genetic Counseling. 23(3): 311-322, 2014.
*9. Roman, L., Meghea, C., Ford, S., Penner, L., Hamade, H., Estes, T., **Williams, K.P.** Determinants of Breast and Cervical Cancer Screening among Black, Latina and Arab Women. Journal of Women's Health 23, 57-64, 2014.
10. **Williams, K.P.,** Templin, T.N. Kin Keeper[SM]: Bringing the Real World to Psychometric Evaluation of Cervical Cancer Literacy Assessments with Black, Latina and Arab Women. Journal of Cancer Education. 28, 738-743, 2013.
*11. McGroarty, E., Jimenez, T., Linley, J., Li Y., Granberry-Russell, P., **Williams, K.P.,** External Funding: Impact on Promotion and Retention of STEM Assistant Professors. Journal of Academic and Business Ethics. 8, 2014
*12. Ford, S., Meghea C., Estes, T., Hamade, H., Lockett, M., **Williams, K.P**. Assessing the Fidelity of the Kin Keeper[SM] Prevention Intervention in African American, Latina and Arab Women. Health Education Research. 29, 158-165,2013.
*13. Ndukwe, E.G., **Williams, K.P**., Sheppard V. Knowledge and Perceptions of Breast and Cervical Cancer Screening among female African Immigrants in the Washington DC Metropolitan Area. Journal of Cancer Education. 28(4): 748-754, 2013.
14. **Williams, K.P.**, Roman, L., Meghea C., Penner, L., Hammad, A., Gardiner, J. Kin Keeper[SM]: Design and Baseline Characteristics of a Community-Based Randomized Controlled Trial Promoting Cancer Screening in Black, Latina, and Arab Women. Journal of Contemporary Clinical Trials. 34, 312-319, 2013.
*15. Williams-Gauss, J., Mabiso, A., **Williams, K.P**. Pap Screening Goals and Perceptions of Pain among Black, Latina, and Arab Women: Steps Toward Breaking Down Psychological Barriers. Journal of Cancer Education 28(2): 367-374, 2013
16. **Williams K.P.**, Templin, T.N., Hines, R.D. Answering the Call: A Functional Health Literacy Tool for Breast Cancer. Journal of Health Communication. 18, 1310-1325, 2013.
17. **Williams, K.P** The Devil is in the Details: Community Based Participatory Research. Journal of Cancer Education. 27(1): 3-4 2012.
18. **Williams, K.P.,** Expanding the Influence of Cancer Education. Journal of Cancer Education. 25(3):275-276. http://www.springerlink.com/content/318709l46q93503t/fulltext.pdf
*19. Arshad, S., **Williams**, **K.P.**, Mabiso, A., Soliman, A.S., Evaluating the Knowledge of Breast Cancer Screening and Prevention of Arab-American Women in Michigan. Journal of Cancer Education. Online May 2010. http://www.springerlink.com/content/8828n0327qn13454/fulltext.pdf
20. **Williams, K.P.**, Mabiso, A., Todem, D., Hill-Ashford, Y., Hamade, H., Palmisono, G., Zambrana, R.E. Differences in Knowledge of Breast Cancer Screening Modalities among African-American, Latina and Arab-American Women. Preventing Chronic Disease. 8:1-8, 2011. http://www.cdc.gov/pcd/issues/2011/jan/pdf/09_0185.pdf

21. **Williams, K.P.,** Mabiso, A., Lo, Y., Penner L. Mammography Screening Trends: The Perspective of African American Women Born Pre/Post World War II. Journal of the National Medical Association. 102:452-459, 2010. http://www.nmanet.org/images/uploads/Publications/OC452.pdf
*22. Mousa, S.M., Brooks, E., Dietrich, M., Henderson, A., McLean, C., **Williams, K.P.** Community Health Workers Speak out about the Kin Keeper[SM] Model. Journal of Cancer Education. 25(3):236-241. http://www.springerlink.com/content/gl1u776h77206587/fulltext.pdf
23. Mabiso, A., **Williams, K.P.**, Todem, D., Templin, T. Longitudinal Analysis of Domain-Level Breast Cancer Literacy among African-American Women. Health Education Research. 25(1):151-161, 2010. http://her.oxfordjournals.org/content/25/1/151.full.pdf+html
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Manuscripts Under Review

*1. Talley, C.H., Yang, L., **Williams, K.P.** Determinant of Factors Associated with Intentions to Obtain Breast Cancer Screening Among Racial/Ethnic Minority Women
*2. Talley, C.H., **Williams, K.P**., Bumpers, H. Assessment of African American Women Undergoing Breast Cancer Diagnostic Evaluation
*3. Yang, L., Meghea, C., Bell, L. Estes, T. **Williams, K.P.** Community-based Participatory Research Data Management for the Kin Keeper[SM] Project
*4. Ford, S., Meghea C., **Williams, K.P**. Many Moving Parts: Evaluation of the Kin Keeper[SM] Cancer Prevention Intervention
5. Asiedu, G.B., Haynes, S.N., **Williams, K.P.** Bondaryk, M.R., Halyard M.Y., Parker, M.W., Balls-Berry, J.E., Pinn, V.W., Radecki-Breitkopf, C. Prevalent Health Concerns among African-American Women: Insight from The Links, Incorporated
*6. Hammad, A., Meghea, c., Litzner, W., Tariq, M., Hamade, H. Vaghela, K., **Williams, K.P.** Immigration Patterns and Breast Cancer Literacy and Breast Screening for Arab Women
*7. Roman, L, Zambrana R.E., Ford, S., Meghea C.I., **Williams, K.P.** Casting a Wider Net: Engaging Community Health Worker Clients and Their Families in Cancer Prevention

Manuscripts in Progress

1. **Williams, K.P.** Meghea, C.I., Talley, C., Todem, D. Ford, S., Roman, L. The Kin Keeper[SM] Intervention: A Community-Based Randomized Controlled Trial
2. **Williams, K.P.,** Dotson, K. Kin Keeper[SM] Model Addresses Epistemic Oppression.

Book Chapters (Peer-Reviewed)

1. Sheppard, V.B., Flynt Wallington, S., **Williams, K.P.**, Lucus, W. A Decision Support Intervention for Black Women Eligible for Adjuvant Systemic Therapy. Cancer Disparities: Causes and Evidence Based Solutions Elk, R., Landrie, H. Springer Publishing Company, NY, NY 2011.
2. **Williams, K.P.**, Hines, R.D., Livingston, J.N. Recruiting African American Women into Chemoprevention Trials: Gail Model as an Education Tool. Female African Americans and Health Research. Nova Science Publishing, NY 2008.
3. **Williams, K.P.**, Kin Keepers: Breast Cancer Prevention for African American Women. Black Families, 4th Edition. McAdoo, H.P. Sage Publications, CA 2007.

Instruments

Williams, K.P. Breast Cancer Literacy Assessment Tool, © 2007.
Williams, K.P. Cervical Cancer Literacy Assessment Tool, © 2007.

Curriculum

1. **Williams, K.P.**, Talley, C., Ford, S. The Kin Keeper[SM] Train the Trainer Manual © Pending
2. **Williams, K.P.**, Lawshe, D.C. The Kin Keeper[SM] Cancer Prevention Intervention Curriculum Guide and Workbook, © 2007.

Reports

1. **Williams, K.P.** May 2011, 2012, 2013, 2014 Kin Keeper[SM]: Reducing Disparities Through Cancer Literacy and Screening. Michigan State University, East Lansing.
2. **Williams, K.P.** November 2010, 2011. Health Disparities: Survey Validation for Black, Latina and Arab Women. Michigan State University, East Lansing.
3. **Williams, K.P.** April 2010. Examining Trust and Cancer Literacy on Breast Cancer Screening. Michigan State University, East Lansing.
4. **Williams, K.P.** November 2009. Health Disparities: Survey Validation. Michigan State University, East Lansing.
5. **Williams, K.P.** August 2009. Breast and Cervical Cancer Screening Patterns of African American Women Age 50 and Older Final Report. Michigan State University, East Lansing.
6. **Williams, K.P.** August 2008. Testing a Family Breast Cancer Prevention Intervention Final Report. Michigan State University, East Lansing.
7. **Williams, K.P.** June 2007. Expanding Cancer Prevention through Translation and Training Final Report. Michigan State University, East Lansing.
8. **Williams, K.P.** October 2006. Kin Keeper[SM] Cancer Prevention Final Report, Michigan State University, East Lansing.
9. **Williams, K.P.** June 2004. The Kin Keeper[SM] Project: Linking with African American Women for Breast Health and Wellness Final Report. Michigan State University, East Lansing.
10. **Williams, K.P.**, Sauer, H., Cornell, W., Hill, T. July 2003. Women's Health Policy in Michigan. Michigan State University, East Lansing.

Book Reviews

1. Black Women Scientists in the United States by Wini Warren. Journal of the History of Science, September 2000.
2. The Interorganizational Community by Robert C. Anderson. The Edward Mellen Press, May 1999.

Editor

1. Journal of Cancer Education, Associate Editor
2. Minority Premedical Newsletter, Center of Excellence in Minority Medical Education & Health, Urban Environmental Curriculum Publication, Resource Development, Undergraduate Senior Project (unpublished)
3. Instructor's Manual, Jackson Community College (unpublished)
4. The Central Region Newsletter for the National Association of Minority Medical Educators

PRESENTATIONS

Invited Speaker

1. **Williams, K.P.** Beginning with the End in Mind. Designing Cancer Interventions for Diverse Populations Panel. International Cancer Education Conference. Tucson, AZ October 22, 2015.
2. **Williams, K.P.** Case Study 2: Kin Keeper[SM] Cancer Prevention Intervention. Society for Behavioral Medicine. Promoting Health Equity Through Dissemination & Implementation Research Panel. San Antonio, TX, April 22, 2015.
3. **Williams, K.P. "**Developing the Kin Keeper[SM] Cancer Prevention Intervention: A Real World Approach." Michigan Urban Center for African American Aging Research. Detroit, MI, June 10, 2013.
4. **Williams, K.P.,** Ford, S., Meghea, C. "Kin Keeper[SM]: A Real World Approach to Addressing Breast and Cervical Cancer Disparities." Centers for Disease Control and Prevention, May 21, 2013.
5. **Williams, K.P.** "Kin Keeper[SM]: A Real World Approach to Addressing Breast and Cervical Cancer Disparities." University of Nebraska Medical Center, April 22, 2013.
6. **Williams, K.P.** "Health Promotion and Disease Prevention." Center for Global Women's Health Inaugural Symposium. University of Pennsylvania School of Nursing, May 11, 2012.
7. **Williams, K.P.** "Kin Keeper[SM], A Model for Cross Training Community Health Workers and Partnering to Conduct Research." University of Michigan Community Health Worker conference. Detroit, MI, August 18, 2011.
8. **Williams, K.P.**, Mabiso, A. "Health Retirement Study: A New Perspective in Mammography Screening." Resource Centers for Minority Aging Research Investigators Meeting. San Francisco, CA, March 15, 2012.
9. **Williams, K.P.** "The Kin Keeper[SM] Cancer Prevention Intervention: Expanding its Utility." University of Michigan Comprehensive Cancer Center Breast Care Education Forum. Ann Arbor, MI, July 6, 2011.
10. **Williams, K.P.** "Developing a Community Based Intervention: Kin Keeper[SM]." Michigan Urban Center for African American Aging Research. Detroit, MI, June 6, 2011.
11. **Williams K.P.** "A Real World Approach to Addressing Breast and Cervical Cancer Disparities." Synergy Medical Alliance. Saginaw, MI, January 6, 2011.
12. **Williams, K.P.,** Templin T.N. "A Female-friendly and Home-based Intervention to Teach African and Middle Eastern Women About Cervical Cancer Prevention." University of Michigan and Cairo University. Cancer in Africa and the Middle East: Downstaging Breast and Cervical Cancer. Cairo, Egypt October 7, 2010.
13. **Williams, K.P.** "Kin Keeper[SM] Cancer Prevention Intervention." 3[Rd] Annual Africa Breast Cancer Conference. Africa Unite in Action: Strengthening Regional Breast Cancer Programs through Integration. Kampala, Uganda, March 15, 2010.
14. **Williams, K.P.** "Kin Keeper[SM] Cancer Prevention with Arab Women." Barbara Ann Karmanos Cancer Institute, Population Science Researchers. Detroit, MI. March 11, 2009.
15. **Williams, K.P.** "Ethnic Differences in Knowledge of Breast Cancer Screening Modalities." Detroit Department of Health and Wellness Promotion Public Health Grand Rounds. Detroit, MI, October 8, 2008.
16. **Williams, K.P.** "Medical Mistrust and Implications for Breast Health for Medically Underserved Women." American Medical Student Association Annual Meeting. Houston, TX, March 13, 2008.
17. **Williams, K.P. "**Using a Family Model to Teach Breast and Cervical Cancer Prevention to Underserved Women." Synergy Medical Alliance. Saginaw, MI, January 11, 2008.
18. **Williams, K.P. "**Kin Keeper[SM] Cancer Prevention Intervention: Clinical Implications." Michigan State University Colleges of Human and Osteopathic Medicine Reproductive Elective. November 28, 2006.
19. **Williams, K.P.** "Translating Research into Practice for Medically Underserved Women." University of Michigan School of Public Health Global Health Seminar, November 8, 2006.

20. **Williams, K.P.** "Conducting Research to Advance Knowledge and Transform Lives." Michigan State University College of Natural Sciences Charles Drew Seminar. October 31, 2006.
21. **Williams, K.P. "**Kin Keeper[SM]: A Model to Teach Black Women and their Family Members About Breast and Cervical Cancer Prevention." American Association for Cancer Research Scientific Symposium Interventions to Address Cancer Disparities, 97th Annual Meeting. Washington, D.C., April 1-5, 2006.
22. **Williams**, **K.P.** "Using Grants to Service Your Clients." Michigan State University School of Social Work Graduate Course. February 2006.
    Williams, K.P. "The Inclusion of Women and Minorities in Research, Challenging Issues for Today's Institution Review Boards." Michigan State University, November 7, 2003.
23. **Williams, K.P. "**Recruiting and Retaining African Americans in Research." Michigan State University, College of Nursing Doctoral Students. June 18, 2003.
24. **Williams, K.P.** "Opportunities for Minority Students at Michigan State University." Minority Student Recruitment in Resource Development. June 22, 1999.
25. **Williams, K.P.** "Trends in Women's Health." Michigan Women's Foundation, Women's Health Initiative Board. Livonia, MI, June 3, 1999.
26. **Williams, K.P.** "Cultural Competency in Medicine and Health." Race in 21st Century, A National Conference. East Lansing, MI, April 9, 1999.
27. **Williams, K.P.** Women as Kin Keepers. National Convention of Delta Sigma Theta Sorority, Inc. New Orleans, LA, August 8- 13, 1998.

Peer-Reviewed Presentations

1. Ford, S., **Williams, K.P.** "Time to Refocus our Knowledge: Differences and Disparities in Cervical Cancer Screening, Incidence, and Mortality Rates in Black and White Women." American Association for Cancer Education Annual. Meeting Clearwater, Fl, October 21-24, 2014.
2. Radecki Breikopf, C., **Williams, K. P.,** Bondaryk M., Halyard, M., Parker, M., Balls-Berry, J., Pinn, V. W., Hayes, S. "Prevalent Health Concerns among African American Women: Insight from The Links, Incorporated. " Women's Health 2014: The 22nd Annual Congress, Washington, DC, April 4-6, 2014.
3. **Williams, K.P. "**What Works? Successes and Barriers to Participant Retention in Longitudinal Community-based Participatory Research." European Association for Cancer Education Meeting, Caen, France, March 26-29, 2014.
4. Smith, D., **Williams,** K.P. Talley, C., "Cervical Cancer Awareness among Black, Latina and Arab Women." Midwest Nursing Research Society 2014 Annual Research Conference. St. Louis, MO , March 27-30, 2014.
5. **Williams, K.P. "**A Real World Approach to Addressing Breast and Cervical Cancer Disparities." Cancer in Africa: Bridging Science and Humanity, AORTIC annual meeting, Durban, South Africa, November 21-23, 2013.
6. Zambrana, R.E., Meghea, C., Lockett, M., **Williams, K.P.** "The Role of Demographic Factors and Family Communication in Cervical and Breast Cancer Literacy by Race and Ethnicity: The Kin Keeper[SM] Trial." American Public Health Association Annual Meeting, Think Global Act Local. Boston, MA, November 2-6, 2013.
7. Hammad, A., **Williams, K.P.** ACCESS's Global Health Model and its Impact through Research Capacity Building – Kin Keeper[SM] Case Study. NAANA 27th International Medical Convention. Health without Boarder: Health Cancer Delivery in the Time of Globalization. Vienna Austria, June 29-July 4, 2013.
8. Roman, L., Meghea, C., Penner, L., Hamade, H., Estes, T., **Williams, K.P.** "Determinants of Breast and Cervical Cancer Screening among Black, Latina and Arab Women." NIH 2012 Summit on the Science of Eliminating Health Disparities. Washington, DC, October 31- November 3, 2012.
9. Zambrana, R., Meghea, C. Lockett, M., Hammad, A., Talley C., **Williams, K.P. "**The Role of Family Communication Practices in Cancer Screening Practices." NIH 2012 Summit on the Science of Eliminating Health Disparities. Washington, DC, October 31- November 3, 2012.

10. Hamade, H., Roman, L., Meghea, C., Estes, T., Lockett, M., Penner, L., **Williams, K.P.** "Cancer Screening and Literacy in Black Latina and Arab Women." Intercultural Cancer Council Biennial Symposium on Minorities, the Medically Underserved and Health Equity. Houston, TX, June 27-July 1, 2012
11. **Williams, K.P.,** Templin, T.N. **"**Psychometric Evaluation of Cervical Cancer Literacy Assessments with Black, Latina and Arab Women." Fourth AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved. Washington, DC, September 18-21, 2011.
12. Lee, C.K., **Williams, K.P. "**The Kin Keeper[SM] Intervention: multiple interventions may be necessary to generate permanent increases in cancer literacy." Fourth AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved. September 18-21, 2011.
13. Williams, J.I., Lee, C.K., **Williams, K.P**. "The Kin Keeper[SM] Intervention: Women Move Beyond Psychological Barriers to Pap Screening." Fourth AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved. Washington, DC, September 18-21, 2011.
14. **Williams, K.P.,** Templin, T. "The Breast Cancer Literacy Assessment Tool: Reliability and Predictive Validity." NINR 25th Anniversary Celebration. Washington, DC, October 13, 2011.
15. Templin, T., **Williams, K.P**. "Psychometric Evaluation of the Breast Cancer Literacy Assessment Tool in Black, Latina and Arab Women: Measurement Invariance and Cultural Diversity." 119th Annual Convention of the American Psychological Association. Washington, DC, August 4-11, 2011.
16. **Williams, K.P.,** Templin, T.N. "New Instrument to Measure Functional Cancer Literacy". The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved American Association for Cancer Research. Miami, FL, September 30-October 3, 2010.
17. Todem, D., **Williams, K.P. "**Design and model for breast cancer literacy outcomes among medically underserved in Michigan. The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved American Association for Cancer Research. Miami, September 30- October 3, 2010.
18. **Williams, K.P.**, Templin, T.N. "Using Modern Psychometric Methods to Standardize Cancer Literacy Assessments with Medically Under Represented Women." 2010 International Cancer Education Conference. San Diego, CA, October 25-27, 2010.
19. **Williams, K.P**., Hill-Ashford, Y., Hendley, T., Robinson-Lockett, M., Hamade, H. "The Other Side of CBPR: University and Community-based Organizations Working to Address Unethical Behavior of Community Health Workers." 2010 International Cancer Education Conference. San Diego, CA, October 25-27, 2010.
20. Hamade, H., Hill-Ashford, Y., Hendley, T., Robinson-Lockett, M., **Williams, K.P.** "The Other Side of CBPR: University and Community-Based Organizations Working to Address Unethical Behavior of Community Health Workers." 2010 BCCCP/WISE Woman Annual Meeting. Traverse City, MI , May 6-7, 2010.
21. Templin**,** T., Rice, V.H., Weglicki, L., Lewandowski, L., Aroian, K., **Williams, K.P.** "Lessons Learned in Adapting and Modifying Self-Report Measures for Ethnic Minority and Culturally Diverse Groups." Abstract for presentation at the Annual Conference of the Midwest Nursing Research Society Meeting. Kansas City, Missouri, April 8-11, 2010.
22. **Williams, K.P.** "Medical Mistrust's Impact on Breast Cancer Screening for African American, Latina and Arab Women." American Association for Cancer Education Annual Meeting, Houston, TX, October 15, 2009
23. Hill-Ashford, Y., **Williams, K.P.** "Utilizing Community Health Workers to Evaluate Cancer Literacy Levels among the African American, Hispanic and Arabic Communities." 2nd Annual Community Health Worker Conference. Grand Rapids, MI, August 25, 2009.
24. Todem, D., **Williams, K.P.** "Hierarchical modeling of binary data with dependence between the design and outcome success probabilities." 57th Session of the International Statistical Institute, Durban, South Africa, August 14-22, 2009.

25. Todem D., **Williams, K.P.** "Modeling exchangeable binary data with dependence between the design and outcome success probabilities." 2009 Joint Statistical Meetings. Washington, DC, August 2-6, 2009.
26. Mabiso, A., **Williams, K.P.** "Medical Mistrust among Black, Latina and Arab Women." Race in the 21st Century 6th National Conference, Health Care and Communities of Color. East Lansing, MI, April 8-10, 2009.
27. **Williams, K.P.,** "Trends in Cancer Screening for African American Women Pre/Post World War II." Resource Centers for Minority Aging Research Investigators Meeting. Birmingham, AL, April 20-21, 2009.
28. **Williams, K.P.,** LaVeist, T., Hammad, A., Mabiso, A. "Examining Medical Mistrust and Cancer Screening among African American, Latina and Arab Women." American Association for Cancer Research Cancer Disparities Meeting. Carefree, AZ, February 4-6, 2009.
29. **Williams, K.P.,** Hammad, A., Mabiso, A. "Measuring Medical Mistrust: Possible Implications for Breast Cancer Screening." International Arab Health Conference. Dearborn, MI, November 6-7, 2008.
30. **Williams, K.P.**, Hammad, A., Mabiso, A. "Kin Keeper℠ Cancer Prevention Intervention: Improving Arab American Women's Breast Cancer Literacy." International Arab Health Conference. Dearborn, MI November 6-7, 2008.
31. **Williams, K.P.**, Mabiso, A., Lawshe, D.C. "Breast Cancer Cervical Cancer Control Program Enrollees Inform Kin Keeper℠ Curriculum." American Association for Cancer Research International Conference in Cancer Prevention Research. Philadelphia, December 6, 2007.
32. Mullan, P.B., **Williams, K.P.**, Lawshe, D., Rivera-Vazquez, O. "Kin Keeper℠ Participants' Evaluation of a Breast and Cervical Cancer Prevention Training Program." American Association for Cancer Education. San Diego, CA, October 13, 2006.
33. **Williams, K.P.**, Reckase, M., Rivera-Vazquez, O. "Filling a Gap: Developing Cancer Literacy Assessment Tools." National Cancer Institute Career Development Workshop. Palm Desert, CA, September 7, 2006.
34. Rivera-Vazquez, O., Hines, R.D., **Williams, K.P.** "Impact of Family History of Cancer Mammography Screening Practices among Latinas." Society of Prevention Research 14th Annual Conference. San Antonio, TX, May 30-June 2, 2006.
35. **Williams, K.P.**, Wulu, J.T., Hines, R.D. "Effects of Family History on Mammography Screening Among African American Women." American Association for Cancer Research Frontiers in Cancer Prevention 4th Annual Meeting. Baltimore, MD, October 30-November 2, 2005.
36. **Williams, K.P.**, Hines, R.D. **"**Using the National Health Interview Survey to Examine the Relationship of Family History of Cancer in Mammography Screening Practices for Asymptomatic African American Women." American Association for Cancer Education 39th Annual Meeting. Cincinnati, OH, September 15-17, 2005.
37. **Williams, K.P.**, Mullan, P.B., Fletcher, F.E. "Working with Lay Health Leaders to Develop Cancer Literacy Assessments for African American Women." American Cancer Society Exploring Models to Eliminate Cancer Disparities among African American and Latino Populations Conference. Atlanta, GA, April 21-22, 2005.
38. **Williams, K.P.**, "African American Women Linking for Breast Health and Wellness, The Kin Keeper Cancer Prevention Intervention Model." American Association for Cancer Education 38th Annual Meeting. Baltimore, MD, October 14-17, 2004.
39. **Williams, K.P.**, "Communicating Breast Health and Wellness to African Americans Across the Life Span." Cancer Culture and Literacy. Clearwater Beach, FL, May20-May 22, 2004.
40. **Williams, K.P.**, Sikorskii, A. "Family Matters in Individual Cancer Prevention Practices among African American Women: Using the National Health Interview Survey." American Society of Preventive Oncology. Washington DC, March 14-16, 2004.
41. Rostant, O., **Williams, K.P.**, Sheppard V. "Impact of a Breast Cancer Diagnosis on the Emotional Health of African American Women." American Public Health Association 131st Annual Meeting. San Francisco, CA, November 15-19, 2003.

42. **Williams, K.P.** "African American Women's Knowledge, Beliefs and Willingness to Participate in a Preventive Breast Cancer Clinical Trial." American Association for Cancer Research Frontiers in Cancer in Cancer Prevention Research Annual Meeting. Phoenix, AZ, October 27, 2003.
43. **Williams, K.P.** "African American Women's Knowledge, Beliefs and Willingness to Participate in a Preventive Breast Cancer Clinical Trial." Michigan Cancer Consortium Annual Meeting. Detroit, MI, October 1, 2003.
44. **Williams, K.P.**, Sheppard, V. "African American Women's Perspective on the Use of Complementary and Alternative Medicine for Cancer Prevention and Treatment: A Pilot Study." American Society of Preventive Oncology. Philadelphia, PA, March 10, 2003.
45. **Williams, K.P. "**Healthy African American Women's Perspective on the Use of Complementary and Alternative Medicine for Cancer Treatment and Prevention: A Pilot Study." American Public Health Association Annual Meeting. Atlanta, GA, October 24, 2001.
46. **Williams, K.P. "**Training of Underrepresented Minority Medical Students to be Culturally Competent." Stakeholders National Meeting for National Minority Health Month. Washington, DC, October 16, 2000.
47. **Williams, K.P. "**Capacity Building: A Strategy to Help Narrow the Health Disparity for African American Women." Sociological Practice Association, Annual Meeting. Washington, DC, August 11, 2000.
48. **Williams, K.P.**, Hurst, R., "African American Women and Cardiovascular Disease: Practical Solutions." CHUMS National Conclave. East Lansing, MI, October 15, 1999.
49. **Williams, K.P.** Organizing Community-based Coalitions: Engaging the Community to Access Information and Services. State Minority Health and State Women's Health Partnership Summit. Department of Health and Human Services, Washington, DC, July 13, 1999.
50. **Williams, K.P.**, Wulu, J., "An Analysis of Community Development Approaches to Cardiovascular Disease Prevention Projects for African Americans." 126th Annual Meeting of American Public Health Association, Washington, DC, November 15-18, 1998.
51. **Williams, K.P.**, Williams, A., Hurst, R., McPhail, J., "Using Focus Groups to Assess the Impact of Community-Based Cardiovascular Disease Prevention Programs in Minority Populations in Michigan." Cardiovascular Health: Coming Together for the 21st Century. San Francisco, CA, February 19, 1998.
52. Pratt, C., Hurst, R., **Williams, K.P.** "Evaluating the Effectiveness of Community-based Cardiovascular Disease Prevention Programs in Michigan." 12th International Interdisciplinary Conference on Hypertension in Blacks. London, UK, July 20-24, 1997.
53. **Williams, K.P.** "An Analysis of Community Development Approaches to Cardiovascular Disease Prevention Projects for African Americans." Michigan State University Department of Resource Development Faculty Seminar. East Lansing, MI, July 14, 1997.

REVIEWER

Proposals

1. Department of Health and Human Services, Center for Scientific Review, National Institutes of Health, Nursing and Related Clinical Sciences Study Section, Charter Member 2011-2018.
2. Department of Health and Human Services, Center for Scientific Review, National Cancer Institute Subcommittee F, Ad Hoc Reviewer, Fall, 2013.
3. Department of Health, England and Cancer Research (UK), National Awareness Early Diagnosis Initiative Guest Reviewer, June, 2010.
4. Department of Health and Human Services, National Institutes of Health, National Institute of Nursing Research, June, 2010. (NRRC 48).
5. Henry Ford Health System, Research Administration, INPHAASE 2010 Requests for Proposals, May, 2010.

6. Department of Health and Human Services, Centers for Disease Control, Health Promotion and Disease Prevention Research Centers Proposals, January, 2009 (Special Emphasis Panel C).
7. Department of Health and Human Services, National Institutes of Health, Community Participation in Research Proposals, November/December 2005, 2006, 2007, ZRG1HOP-U (91) S Review Committee.
8. Susan G. Komen Breast Cancer Foundation, Risk and Prevention, Epidemiology Proposals, December, 2005.
9. Michigan Women's Foundation. Social Impact Grants, March, 2003, August, 2005.
10. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau, Integrated Comprehensive Women's Health Services in State MCH Programs, May, 2001; August, 2002.
11. Department of Health and Human Services, National Institutes of Health, Minority Research Training Applications, July, 1999.
12. National HIV Prevention Conference, Abstracts, May, 1999.
13. Department of Health and Human Services, National Institute for Occupational Safety and Health, Center for Disease Control and Prevention, Proposals, July, 1998.

Manuscripts

1. American Journal of Preventive Medicine, Editorial Board Member
2. Journal of Cancer Education, Associate Editor
3. Journal of Health Communications, 2014
4. Journal of National Medical Association, 2007, 2008, 2009, 2010, 2012
5. Journal of Cancer, Epidemiology and Biomarkers, 2008
6. Journal of Health Education Research, 2008, 2009, 2010
7. Journal of Psycho-Oncology, 2008, 2009, 2010, 2011, 2014
8. Journal of Cancer, 2008, 2009, 2014
9. Journal of American Medical Association (JAMA), 2009, 2010
10. Journal of Healthcare for the Poor and Underserved, 2009, 2014
11. Journal of Women's Health, 2010, 2011, 2014
12. Journal of General Internal Medicine, 2010, 2012
13. Journal of Contemporary Trials, 2012
14. Journal of Health Communications, 2013

SERVICE

Academic

Obstetrics, Gynecology & Reproductive Biology, Executive Committee, Member
Obstetrics, Gynecology & Reproductive Biology, Tenure Promotion Committee, Member
College of Human Medicine, Dean's Search Committee
College of Human Medicine, Diversity & Inclusion Task Force, Member
College of Human Medicine, Grievance Committee, Member
College of Human Medicine, Scholarship Committee, Member
Advanced Baccalaureate Learning Experience Program (ABLE), Admissions Committee, Member
Intramural Research Grants Program, Reviewer
Michigan State University Black Faculty and Administrators Association, Member
Michigan State University, Women's Advisory Committee to the Provost, Member
Michigan Women's Foundation, Board of Directors
Resource Development Undergraduate Curriculum Committee
Resource Development Graduate Organization, Member

Student Scholarship Selection Committee, Member
University Committee on Faculty Tenure, Graduate Student Member

Professional
Academy Health, Member
American Association for Cancer Education, Executive Board Member, President
American Association for Cancer Research, Active Member
American Public Health Association, Member
American Society of Preventive Oncology, Member
Healthcare Advocacy for Women Initiative, Steering Committee Member
Journal of Cancer Education, Editorial Board Member, Associate Editor
Michigan Cancer Consortium, Breast Cancer Advisory Committee and Improving African American Enrollment in Clinical Trials Task Force
Michigan Office of Services to the Aging, Older Women's Health Care, Steering Committee Member
Michigan Women's Health Advocacy Network, Board Chair
Michigan Women's Foundation, Board Member
Michigan State Medical Society, Women's Health Conference Steering Committee
Michigan Stroke Initiative, Member
National Association of Black Journalists, Member
National Association of Minority Medical Educators, Communications Committee
Priority Health, Quality Integration Committee
Society for the Analysis of African American Public Health Issues, Board Member
Society of Professional Journalists, Member
Society for Values in Higher Education, 1994 Fellow
Sociological Practice Association, Board Member
Susan G. Komen Breast Cancer Foundation Greater Lansing Affiliate, Board Member
Statewide Women of Color Health Conference Planning Committee, Co-Chair
University Alabama Birmingham Cancer Prevention Control Training Program, External Advisor
U.S. Public Health Service, Office on Women's Health, Minority Women's Health Panel of Experts, Co-Chair
U.S. Public Health Service's Office on Women/Office of Minority Health, Leadership Summit Committee
Year of the Women's Health Initiative Statewide Task Force, Member

Community
Delta Sigma Theta Sorority, Inc. (public service sorority), Executive Board Member, Lansing Alumnae
Harvest House (Homeless Shelter), Board of Directors, Vice President
Economic Crisis Center (Transitional Shelter), Board of Directors
Ingham County Women's Commission, Commissioner, Chair of Awards Program
Jackson County Fair Housing Center, Board of Directors, Member
Jackson County Girl Scouts, Junior Girl Scout Leader
Lansing Woman's Club, Member
Michigan Council, Delta Sigma Theta Sorority, Inc., Chair Statewide Social Action Planning Committee
Michigan Protection and Advocacy Services, Board of Directors, Treasurer, Finance Committee Chair
National Association for the Advancement of Colored People, Member
Prayer Chapel COGIC, Sunday School Superintendent, Member
South Central Education Association (community educational center), Board of Directors, Secretary
Susan G. Komen Breast Cancer Foundation Greater Lansing Affiliate, Board President
The Links, Incorporated, Lansing/East Lansing President, Central Area Health and Human Services Chair
Union Baptist Church, Sunday School Teacher, Member
United Negro College Fund, Lansing Campaign, Executive Board Member, Secretary
YWCA of Greater Lansing, Board Member, Chair, YWCA/Sparrow Health Systems Advisory Committee
Zonta Club of Lansing, Member

DUKE UNIVERSITY MEDICAL CENTER

CURRICULUM VITAE

Date Prepared: March 2012

Name: Neil Lee Spector, M.D.

Primary academic department: Medicine

Present academic rank and title: Associate Professor Medicine (primary appointment) and Pharmacology/Cancer Biology (secondary appointment), Co-Director of the Experimental Therapeutics Program (Duke Cancer Institute); Associate Director Clinical Research, Breast Cancer Program (Duke Cancer Institute)

Date and rank of first Duke Faculty appointment: 9/1/06, Associate Professor

Medical Licensure: [redacted] (first obtained 06/30/99; latest 06/30/11)

Specialty certification and dates:

- American Board of Internal Medicine (1987; certificate 106726)
- American Board of Hematology (1988; certificate 106726)
- American Board of Medical Oncology (1989; certificate 106726)

Date of birth: [redacted] Philadelphia/PA/USA

Citizen of: USA

Education	Institution	Date (Year)	Degree
High School	Livingston High School	1974	
College	U. North Carolina-Chapel Hill	1978	B.A.
Medical School	New Jersey Medical School	1982	M.D.

Scholarly societies: Phi Beta Kappa; Alpha Omega Alpha

Professional training and academic career

Institution	Position/Title	Dates
Parkland Hospital (U. Texas Southwestern Medical Center)	PGY1-3/Medicine	1982-1986

Professional training and academic career

Institution	Position/Title	Dates
Parkland Hospital	PGY1/Neurology	1983-1984
Massachusetts General Hospital (Harvard Medical School)	Fellow/Heme-Oncology	1986-1988
Dana-Farber Cancer Institute (Harvard Medical School)	Fellow/Bone Marrow Transplant	1988-1989
Dana-Farber Cancer Institute	Instructor/Medicine	1989-1993
U. Miami School of Medicine	Assistant Professor/Medicine (Division Hematology/Oncology)	1993-1998
GlaxoSmithKline	Director of Exploratory Medical Sciences-Oncology	1998-2006
U. North Carolina-Chapel Hill	Adjunct Associate Professor/Medicine (Division Hematology/Oncology)	1998-2006
Duke University Medical Center	Associate Professor Medicine	2006-present

Publications:

Refereed journals:

1. Spector S, Spector NL, & Almeida M. "Radioimmunoassay for desmethylimipramine" *Psychopharm. Comm*. 1976; **1**: 421-429.
2. Spector S, Spector NL et al. "Correlation between plasma and cerebrospinal fluid levels of imipramine." *Arch. Gen. Psych*. 1976; **33**: 1109-1111.
3. Spector NL, Freedman AS, Freeman G, Segil J, Whitman JF, Welch WJ, & Nadler LM. "Activation Primes Human B Lymphocytes To Respond To Heat Shock." *J. Exp. Med*. 1989; **170**: 1763-1768.
4. Spector NL, Samson W, Gribben JG, Urba W, Welch WJ, & Nadler LM. "Growth Arrest of Human B Lymphocytes Is Accompanied by Induction of The Low Molecular Weight Mammalian Heat Shock Protein (Hsp28)." *J. Immunol*. 1992; **148**: 1668-1673.
5. Soiffer RJ, Murray C, Anderson KC, Freedman AS, Takvorian T, Robertson MJ, Spector NL, Coral F, Nadler LM, & Ritz J. "Prevention of

Graft-versus-Host Disease by Selective Depletion of CD6 Positive T Lymphocytes From Donor Bone Marrow." *J. Clin. Oncol.* 1992; **10**: 1191-1200.

6. Grossbard ML, Freedman AS, Ritz J, Coral F, Spector NL, Lambert JM, Blattler WA, Taylor JA, & Nadler LM. "Serotherapy of B-Cell Neoplasms with Anti-B4-Blocked Ricin: A Phase I Trial of Daily Bolus Infusion." *Blood* 1992; **79**: 576-585.
7. Grossbard ML, Lambert JM, Goldmacher VS, Spector NL, Kinsella J, Coral F, Epstein CL, Freedman AS, & Nadler LM. "Anti-B4-blocked ricin: a Phase I trial of 7-day continuous infusion in patients with B-cell malignancies." *J. Clin. Oncol.* 1993; **11**: 726-737.
8. Rabinowe SN, Soiffer RJ, Gribben JG, Freedman AS, Spector NL, Grossbard ML, Anderson KC, Robertson MJ, Ritz J, & Nadler LM. "Autologous and Allogeneic Bone Marrow Transplantation for Poor Prognosis Patients with B-Cell Chronic Lymphocytic Leukemia." *Blood* 1993; **82**: 1366-1376.
9. Anderson KC, Andersen J, Soiffer R, Freedman AS, Rabinowe SN, Robertson MJ, Spector NL, Blake K, Mauch P, Nadler LM, & Ritz J. "Monoclonal antibody-purged bone marrow transplantation therapy for multiple myeloma." *Blood* 1993; **82**: 2568-2576.
10. Soiffer RJ, Roy DC, Murray C, Anderson KC, Freedman AS, Spector NL, Robertson MJ, Pesek K, Nadler LM, & Ritz J. "Monoclonal antibody-purged autologous bone marrow transplantation in adults with acute lymphoblastic leukemia at high risk of relapse." *Bone Marrow Transplant*. 1993; **12**: 243-251.
11. Freedman AS, Takvorian T, Mauch P, Rabinowe SN, Anderson KC, Soiffer RJ, Spector NL, Ritz J, & Nadler LM. "Autologous Bone Marrow Transplantation in Poor Prognosis Intermediate Grade and High Grade B-Cell Non-Hodgkin's Lymphoma in First Remission: A Pilot Study." *J. Clin. Oncol*. 1993; **11**: 931-936.

12. Gribben JG, Neuberg D, Freedman AS, Gimmi CD, Pesek KW, Woo S, Spector N, & Nadler LM. "Detection by polymerase chain reaction of residual cells with the bcl-2 translocation is associated with increased risk of relapse after autologous bone marrow transplantation for B-cell non-Hodgkin's Lymphoma." *Blood* 1993; **81**: 3449-3457.
13. Spector NL, Ryan C, Samson W, Levine H, Nadler LM, & Arrigo AP. "Hsp28 is a unique marker of growth arrest during macrophage differentiation of HL60 cells." *J. Cell. Physiol*. 1993; **156**: 619-625.
14. O'Day SJ, Rabinowe SN, Neuberg D, Freedman AS, Soiffer RJ, Spector NL, Robertson MJ, Anderson KC, Pesek K, Ritz J, & Nadler LM. "A phase II study of continuous infusion recombinant human granulocyte-macrophage colony-stimulating factor as an adjunct to autologous bone marrow transplantation for patients with non-Hodgkin's lymphoma in first remission." *Blood* 1994; **83**: 2707-2714.
15. Spector NL, Mehlen P, Ryan C, Samson W, Levine H, Nadler LM, & Arrigo AP. "Novel Regulation of the 28 kDa Heat Shock Protein By Retinoic Acid During Differentiation of Human Leukemic Cells." *FEBS Letts*. 1994; **337**: 184-188.
16. Spector NL, Hardy L, Ryan C, Miller WH Jr, Humes JL, Nadler LM, & Luedke E. "The 28 kDa Mammalian Heat Shock Protein, A Novel Substrate Of A Growth Regulatory Protease Involved In Differentiation of Human Leukemia Cells." *J. Biol. Chem*. 1995; **270**: 1003-1006.
17. Hardy L, Goodman M, Vasquez A, Chauhan D, Anderson KC, Voellmy R, & Spector NL. "Activation signals regulate heat shock transcription factor 1 in human B lymphocytes." J. *Cell. Physiol*. 1997; **170**: 235-240.
18. Koya R, Anderson J, Fernandez H, Goodman M, Spector N, Smith R, Hanlon J, & Cassileth PA. "Analysis of the value of empiric vancomycin administration in febrile neutropenic peripheral blood stem cell transplants." *Bone Marrow Transplant* 1998; **21**: 923-926.

19. Rao J, Zhang F, Donnelly RJ, Spector NL, & Studzinski GP. "Truncation of Sp1 transcription factor by myeloblastin in undifferentiated HL60 cells." *J. Cell. Physiol*. 1998; **175**: 121-128.
20. Goodman M*, Spector NL*, Rodrigues G, & Cassileth P. "Interleukin-2 therapy for advanced chronic myeloid leukemia." *Leukemia* 1998; **12**: 1682-1684. (*equal contributor)
21. Xia W, Voellmy R, & Spector NL. "Sensitization of tumor cells to Fas killing through overexpression of heat-shock transcription factor 1." *J. Cell. Physiol*. 2000; **183**: 425-431.
22. Xia W, Spector S, Hardy L, Saluk A, Alemane L, & Spector NL. "Tumor selective G2/M cell cycle arrest and apoptosis of epithelial and hematological malignancies by BBL22, a benzazepine." *Proc. Natl. Acad. Sci. USA* 2000; **97** (13): 7494-7499.
23. Xia W, Mullin R, Keith B, Liu L-H, Alligood K, Ma H, Rusnak DW & Spector NL. "Anti-tumor activity of GW2016, a dual tyrosine kinase inhibitor blocks EGF activation of EGFR/erbB2 and downstream Erk1/2 and AKT pathways." *Oncogene* 2002; **21**: 6255-6263.
24. Xia W, Hardy L, Liu L, Zhao S, Goodman M, Voellmy R, & Spector NL. "Concurrent Exposure to Heat Shock and H7 Synergizes to Trigger Breast Cancer Cell Apoptosis while Sparing Normal Cells." *Breast Cancer Res. Treat*., 2003; **77** (3): 233-243.
25. Czito BG et el., "A Phase I trial of preoperative eniluracil plus 5-fluorouracil and radiation for locally advanced or unresectable adenocarcinoma of the rectum and colon." *Int. J. Rad. Oncology Biol. Phys*., 2004; **58** (3): 779-785.
26. Xia W, Liu L-H, Ho P, & Spector NL. "Truncated ErbB2 receptor (p95ErbB2) is regulated by heregulin through heterodimer formation with ErbB3 yet remains sensitive to the dual EGFR/ErbB2 kinase inhibitor GW572016." *Oncogene* 2004; **23**: 646-653.
27. Bence AK, Anderson EB, Doukas MA, DeSimone PA, Davis GA, Smith DA, Koch KM, Stead AG, Mangum S, Spector NL, Hsieh S, & Adams

VR. “Phase I pharmacokinetic studies evaluating single and multiple doses of oral GW572016, a dual EGFR-ErbB2 inhibitor, in healthy subjects.” *Investigational New Drugs* 2005; **23**: 39-49.

28. Spector NL, Xia W, Burris HA, Hurwitz H, E. Claire Dees, Dowlati A, O’Neil B, Overmoyer B, Liu L, Marcom K, Blackwell K, Smith DA, Koch K, Mangum SG, Stead A, Greco FA, Harris J, & Bacus SS. “A Study of the biological effects of GW572016, a reversible inhibitor of EGFR (ErbB1) and ErbB2 tyrosine kinases, on tumor growth and survival pathways in patients with advanced malignancies.” *J. Clin. Oncol*., 2005; **23**: 1-11.
29. Xia W, Gerard C, Lui L, Baudson N, Ory T, & Spector NL. “Lapatinib (GW572016), a small molecule inhibitor of ErbB1 and ErbB2 tyrosine kinases synergizes with anti-ErbB2 antibodies to inhibit mediators of tumor cell survival and induce apoptosis in ErbB2 overexpressing breast cancer cells.” *Oncogene*, 2005; **24**: 6213-6221.
30. Burris H, Dees C, Hurwitz H, Dowlati A, Blackwell K, Marcom K, Overmoyer B, Smith D, Koch K, Stead A, Mangum S, Harris J, & Spector NL. “A phase I safety, pharmacokinetic, and clinical activity study of lapatinib (GW572016), a reversible inhibitor of ErbB1 and ErbB2 tyrosine kinases in heavily pre-treated patients with metastatic carcinomas.” *J. Clin. Oncol*. 2005; **23**: 5305-5313.
31. Kelly H, Graham M, Humes E, Dorflinger LJ, Boggess KA, O’Neil BH, Harris J, Spector NL, & Dees C. “Delivery of a healthy baby after first-trimester maternal exposure to lapatinib.” *Clin. Breast Cancer* 2006; **7**: 339-341
32. Xia W, Bisi J, Strum J, Liu L, Carrick K, Graham KL, Hardwicke MA, Treece AL, Bacus S, & Spector NL. “Regulation of survivin by ErbB2 signaling: Therapeutic implications for ErbB2-overexpressing breast cancers.” *Cancer Res*., 2006; **66**: 1640-1647.

33. Bacus S, Yarden Y, Xia W, & Spector NL. "Rational Development of Targeted Cancer Therapies Using Biomarkers." *Laboratory Medicine* 2006; **37**: 482-489.
34. Xia W, Bacus S, Hegde P, Husain I, Strum J, Liu L, Paulozzo G, Trusk P, Lyass L, & Spector NL. "A model of acquired autoresistance to ErbB2 tyrosine kinase inhibitors and a therapeutic strategy to prevent its onset in breast cancer." *Proc. Natl. Acad. Sci. USA* 2006; **103**: 7795-7800.
35. Spector N, Xia W, El-Hariry I, Yarden Y, & Bacus S. "Small Molecule HER-2 Tyrosine Kinase Inhibitors." *Breast Cancer Res*. 2007; **9**: 205-210.
36. Bacus S, Hortobagyi G, Yarden Y, & Spector NL. "The Era of ErbB Receptor Targeted Therapies: Advances Towards Personalized Medicine." *Personalized Medicine* 2005; **2**: 301-315.
37. Xia W, Husain I, Liu L, Bacus S, Saini S, Spohn J, Pry K, Westlund R, Stein S, & Spector NL. "Lapatinib anti-tumor activity is not dependent upon PTEN in ErbB2-overexpressing breast cancers." *Cancer Res*., 2007; **67**: 1170-1175.
38. Spector N, Yarden Y, Smith B, Lyass L, Trusk P, Pry K, Hill JE, Xia W, Seger R, & Bacus SS. "Activation of the AMPK by HER2/EGFR tyrosine kinase inhibitor protects cardiac cells." *Proc. Natl. Acad. Sci. USA* 2007; **104**: 10607-10612.
39. Katz M, Amit I, Citri A, Shay T, Carvalho S, Lavi S, Milanezi F, Lyass L, Amariglo N, Spector NL, Lo S, Schmitt F, Bacus SS, & Yarden Y. "A reciprocal tensin-3-cten switch mediates EGF-driven mammary cell migration." *Nat. Cell Biol*. 2007; **9**: 961-969.
40. Johnston S, Trudeau M, Kaufman B, Boussen H, Blackwell K, Lorusso P, Lombardi DP, Ahmed SB, Citrin DL, DeSilvio ML, Harris J, Salazar V, Zaks TZ, & Spector NL. "Targeting HER2 in advanced inflammatory breast cancer with lapatinib monotherapy: A phase II study with biomarker profiles that predict for response." *J. Clin. Oncol*. 2008; **26**: 1066-1072.

40. Spector N. “Treatment of metastatic ErbB2+ breast cancer options following progression on trastuzumab including management of brain metastases.” *Clin. Breast Cancer* 2008; **14:** 6730-6734.
41. Osada T, Chong G, Tansik R, Hong T, Spector N, Kumar R, Hurwitz HI, Dev I, Nixon AB, Lyerly HK, Clay T, Morse MA. “The effect of anti-VEGF therapy on immature myeloid cell and dendritic cells in cancer patients.” *Cancer Immunol Immunother*. 2008; **57**: 1115-1124.
42. Chen FL, Xia W, & Spector NL. “Acquired resistance to small molecule ErbB2 tyrosine kinase inhibitors” *Clin Cancer Res*. 2008; 14: 6730-6734.
43. Pegram M, Perez EA, Piccart M, Spector N. “Expert roundtable: emerging questions in ErbB2-positive breast cancer.” *Clin Breast Cancer*, 2008; Suppl **3**:S131-41.
44. Spector NL & Blackwell KL. “Understanding the mechanisms behind trastuzumab therapy for human epidermal growth factor factor receptor 2-positive breast cancer.” *J. Clin. Oncol*., 2009 Dec 1;**27**(34):5838-47. Epub 2009 Nov 2. Review.
45. Morse MA, Wei J, Hartman Z, Xia W, Ren XR, Lei G, Barry WT, Osada T, Hobeika AC, Peplinski S, Jiang H, Devi GR, Chen W, Spector N, Amalfitano A, Lyerly HK, & Clay TM. “Synergism from combined immunologic and pharmacologic inhibition of HER2 in vivo.” *Int J Cancer*, 2009 Oct 23. [Epub ahead of print]
46. Burris HA 3rd, Taylor CW, Jones SF, Koch KM, Versola MJ, Arya N, Fleming RA, Smith DA, Pandite L, Spector N, & Wilding G. “A Phase I and pharmacokinetic study of oral lapatinib administered once or twice daily in patients with solid malignancies.” *Clin Cancer Res*., 2009 Nov 1;**15**(21):6702-8. Epub 2009 Oct 13.
47. Kaufman B, Trudeau M, Awada A, Blackwell K, Bachelot T, Salazar V, DeSilvio M, Westlund R, Zaks T, Spector N, & Johnston S. “Lapatinib monotherapy in patients with HER2-overexpressing relapsed or refractory inflammatory breast cancer: final results and survival of the expanded

HER2+ cohort in EGF103009, a phase II study." *Lancet Oncol*., 2009 Jun;**10**(6):581-8. Epub 2009 Apr 24.

49. Xia W, Bacus S , Husain I, Liu L, Zhao S, Liu Z, Moseley MA III, Thompson JW, Chen KL, Koch KM, & Spector, NL. "Resistance to ErbB2 tyrosine kinase inhibitors in breast cancer is mediated by calcium-dependent activation of RelA." *Mol. Cancer Ther.*, 2010 Feb;**9**(2):292-9. Epub 2010 Feb 2.
49. Boussen H, Cristofanilli M, Zaks T, DeSilvio M, Salazar V, & Spector NL. "Phase II Study to Evaluate the Efficacy and Safety of Neoadjuvant Lapatinib in Combination With Paclitaxel in Patients With Newly Diagnosed Inflammatory Breast Cancer." *J. Clin. Oncol*., 2010 Jul 10;**28**(20):3248-55. Epub 2010 Jun 7.
50. Hartman ZC, Wei J, Osada T, Glass O, Lei G, Yang XY, Peplinski S, Kim DW, Xia W, Spector N, Marks J, Barry W, Hobeika A, Devi G, Amalfitano A, Morse MA, Lyerly HK, & Clay TM. "An adenoviral vaccine encoding full-length inactivated human Her2 exhibits potent immunogenicity and enhanced therapeutic efficacy without oncogenicity." *Clin Cancer Res*. 2010 Mar 1;**16**(5):1466-77. Epub 2010 Feb 23.
51. Xia W, Liu Z, Zong R , Liu L[1], Zhao S, Bacus S, Mao Y , He J, Wulfkuhle JD, Petricoin III EF, Osada T, Yang X, Hartman Z, Clay T, Blackwell K, Lyerly K,& Spector NL. "Truncated ErbB2 expressed in tumor cell nuclei contributes to acquired therapeutic resistance to ErbB2 kinase inhibitors." *Mol. Cancer Ther*. 2011 Aug;**10**(8):1367-74. Epub 2011 Jun 14.
52. Il'yasova D, Siamakpour-Reihani S, Akushevich I, Akushevich L, Spector NL, & Schildkraut J. "What can we learn from the age-and race/ethnicity-specific rates of inflammatory breast cancer?" *Breast Cancer Res and Treat*. (in press).

53. Cheng Q, Chang JT, Geradts J, Neckers LM, Haystead T, Spector N, & and Lyerly HK. "Amplification and high-level expression of HSP90 marks aggressive phenotypes of HER2 negative breast cancer." *Breast Cancer Res.* (in press).

54. Xia W, Petricoin III EF, Zhao S, Liu L, Osada T, Cheng Q, Wulfkuhle JD, Yang X, Gallagher RI, Clay T, Bacus S, Lyerly HK, &Spector NL. "Resistance to HER tyrosine kinase inhibitors is mediated by heregulin autocrine feedback loop signaling." (submitted).

Non-refereed publications: NA

Chapters in books:

1. Handbook of Immunohistochemistry and in situ Hydridization of Human Carcinomas, Volume 1 Molecular Genetics; Lung and Breast Carcinomas. "Role of Immunohistochemical Expression of AKT Protein in Breast Carcinoma" Bradley L. Smith, Debbie Altomare, Neil L. Spector, and Sarah S. Bacus. pp. 307-319. M.A. Hayat (Editor), Elsevier Academic Press, 2004.

Books: NA

Non-authored publications: NA

Other: a. Published scientific reviews (for mass distribution): NA

b. Selected abstracts:

1. Xia W, Mullin RJ., Keith BR, Rusnak DW, Alligood KJ, Owens G, Murray DM, Crosby RM, Finlay C, Gilmer TM, Lackey K, Knight WB, Lucas S, & Spector NL. "GW572016, a potent, reversible, dual inhibitor of erbB2 and EGFR tyrosine receptor kinases: effects on receptor tyrosine

autophosphorylation state, downstream signaling intermediaries, and in vivo anti-tumor activity" Proc. Am. Assoc. Cancer Res. 2001; 3625a.

2. Xia W, Mullin RJ, Keith BR, Gilmer TM, Lacky K, Knight WB, Lucas S, & Spector NL. "Effect of GW2016, a dual inhibitor of erbB2 and EGFR tyrosine receptor kinases on EGF induced receptor tyrosine autophosphorylation state and downstream signaling pathways" EORTC/AACR/NCI Oct. 2001.
3. Blackwell KL, Spector N, Snyder SA, Marks J, Xia W, Liu L, Broadwater G, McDonnell DP & Dewhirst MW. "GW572016, a novel dual EGFR/Her-2 small molecule, tyrosine kinase inhibitor induces regression and significant growth delay in tamoxifen-resistant, MCF-7 derived tumors" San Antonio Breast Conference 2002.
4. Burris H, Taylor C, Jones S, Pandite L, Smith, D, Versola M, Stead A, Whitehead B, Spector N, & Wilding G. "EGF10003: A Phase I Study of GW572016 in Patients with Solid Tumors" ASCO 2003
5. Tansik R, Hong T, Spector N, Kumar R, Osada T, Morse M, Hurwitz H, & Dev I. "Circulating endothelial cells and other biomarkers of angiogenesis in patients with lung, breast, and colorectal carcinomas" ASCO 2003
6. Spector N, Raefsky E, Hurwitz H, Hensing T, Dowlati A, Dees C, O'Neil B, Koch K, Smith DA, Mangum S & Burris HA. "Safety, Clinical Efficacy, and Biologic Assessments from EGF10004: A Randomized Phase Ib Study of GW572016 for Patients with Metastatic Carcinomas Overexpressing EGFR or ErbB2" ASCO 2003
7. Bacus SS, Beresford PJ, Yarden Y, Spector N, & Smith B. "The use of predicting factors and surrogate markers in patients' cancer biopsies treated with targeted antibodies to ErbB receptors and ErbB tyrosine kinase inhibitors" ASCO 2003
8. Koch KM, Lee D, Mangum S, Stead A, Versola M, Burris HA, Wilding G, Taylor C, Spector N, & Smith DA. "Pharmacokinetics of GW572016

in an Ascending Dose Tolerability Study of Phase I Cancer Patients" " European J. of Cancer, Vol. 1, Suppl. 5, 559a, 2003

9. Bacus S, Smith B, Maltzman W, Yarden Y, & Spector N. "Differences in response to breast cancer molecular profiles of patients likely to respond to either tyrosine kinase inhibitors or to ErbB targeted therapies" AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, Boston 2003
10. Burris H, Hurwitz H, Dees C, Dowlati A, Blackwell K, Ellis M, Overmoyer B, Jones S, Willcutt N, Smith D, Harris J & Spector N. "EGF10004: A randomized multicenter phase Ib study of the safety, biological activity, and clinical efficacy of the dual kinase inhibitor GW572016" San Antonio Breast Conference 2003
11. Bacus SS, Smith B, Yarden Y, & Spector N. "Differences in response of breast cancer molecular profiles of patients likely to respond to either tyrosine kinase inhibitors or to erbB targeted therapies" ASCO 2004
12. Burris H, Hurwitz H, Dees C, Dowlati A, Smith D, Koch KM, Mangum S, Harris J, & Spector N. "Efficacy, safety and tolerability of GW572016 in a EGF10004, a Phase IIa study of heavily pretreated patients with metastatic carcinomas" ASCO 2004
13. Xia W, Liu L, Ho P, & Spector N. "Truncated ErbB2 receptor (p95ErbB2) is regulated by heregulin through heterodimer formation with ErbB3 yet remains sensitive to the ErbB1/ErbB2 kinase inhibitor GW572016" AACR 2004
14. Versola M, Burris HA, Jones S, Wilding G, Taylor C, Pandite L, Smith DA, Stead A, & Spector N. "Clinical activity of GW572016 in EGF10003 in patients with solid tumors" ASCO 2004
15. Burris H, Bacus S, Hurwitz H, Dees C, Dowlati A, Smith D, Mangum S, Harris J, & Spector N. "The biological effects of GW572016 (lapatinib) on tumor growth and survival pathways in cancer patients" ASCO 2004

16. Xia W, Liu L, Gerard C, Baudson PN, Ory T, Ho P, & Spector N. "The biological effects of GW572016 (lapatinib) on tumor growth and survival pathways in cancer patients" ASCO 2005.
17. Spector NL, Blackwell K, Hurley J, Harris JL, Lombardi D, Bacus S, Ahmed B, Boussen H, Frikha M, & Ayed FB. "EGF103009, a phase II trial of lapatinib monotherapy in patients with relapsed/refractory inflammatory breast cancer (IBC): Clinical activity and biological predictors of response. J. Clin. Oncol. (2006 ASCO Annual Meeting Proceedings) Part 1, Vol. 24, No. 18S, 502a
18. Xia W, Bacus S, Hedge P, Husain I, Strum J, Liu L, Paulazzo G, Harris J, &Spector N. "Autoresistance to ErbB2 kinase inhibitors: Eucidating mechanisms and identifying strategies to prevent its onset in breast cancer" J. Clin. Oncol. (2006 ASCO Annual Meeting Proceedings) Part 1, Vol. 24, No. 18S, 2075a
19. Bacus S, Hill J, &Spector N. "Therapeutic implications for acquired resistance and heart toxicity using targeted therapy to erbB2" J. Clin. Oncol. (2006 ASCO Annual Meeting Proceedings) Part 2, Vol. 24, No. 18S, 3084a

Editorial, position, and background papers: NA

Consultant appointments: No formal consulting contracts but currently working with the following companies and specific projects:

- GlaxoSmithKline
- Syndax
- Serenex
- Millennium/Takeda

Professional awards and special recognitions:

- Claudia Adams Barr Award in Cancer Research (Dana-Farber Cancer Institute) 1991

- Stanley Glaser Award in Cancer Research (U. Miami School of Medicine) 1994
- GSK R&D Recognition Award (Platinum Award Level): Recognition of outstanding research/clinical efforts in the development of lapatinib (2003)
- GSK R&D Recognition Award (Silver Award Level): Recognition of critical contributions to the development of nelarabine from 1997-2001 (2005)
- Selected as a Komen Scholar (one of the 50 top breast cancer researchers in the world): 2010-present
- R. Wayne Rundles Award (Duke Comprehensive Cancer Center) (2008)
- The Wendell Rosse Teaching Award 2010-2011 (Duke University Medical Center)

Patents

1. Title: PREDICTIVE MARKERS IN CANCER THERAPY
PCT publication No.: WO04/000094
US Patent Application No.: 10/529922
US Publication No.: US2006-0094068
Inventors: Myra Herrle, Leone E. Kirk , Neil Spector, Michael Stocum, Wenle Xia, Sarah Bacus
Also filed in: Europe,
GSK File No. PU4995

2. Title: CANCER TREATMENT METHOD COMPRISING ADMINISTERING AN ERB-FAMILY INHIBITOR AND A RAF AND/OR RAS INHIBITOR
PCT Publication No.: WO03/086467
US Patent Application No.:10/510542
US Publication No.: US2005-0176740
Inventors: Neil Spector, Wenle Xia
Also filed in Europe, Japan
GSK File No. PU4725

3. Title: CANCER TREATMENT METHOD
PCT Publication No. WO02.056912

US Patent Application No.: 10/466290
US Publication No.: 2004-0053946
Inventors: Karen Lackey, Neil Spector, Edgar Wood, Wenle Xia
Also filed in Japan, Granted in Europe (EP patent No. 1353693)
GSK File No. PU4257

4. Title:TREATMENT OF CANCERS EXPRESSING p95 ErbB2
PCT Publication No.WO2005/011607
US Patent Application No.10/567012
US Publication No. (not published yet)
Inventors: Neil Spector, Wenle Xia
Also filed in: Europe
GSK File No. PR60419

5. Title: LOCALIZATION OF BIOMARKERS AS PREDICTIVE FOR RESPONSE TO GW572016
GSK File No. PR60446P
Inventors: Neil Spector, Sarah Bacus

Organizations and participation:

- Past member of ASH
- Current member of AACR

Teaching responsibilities including continuing education:

- Teaching hematology/oncology fellows at the University of Miami School of Medicine (1993-1998)
- Attending the hematology/oncology fellows clinic at the University of North Carolina-Chapel Hill (2000-2006)
- GSK mentor for fellows participating in the Duke-GSK oncology fellowship program (1998-2006)
- Coordinating SOS lecture series in the DCCC (Current)
- Developing the agenda for the AAA (Accelerated AntiCancer Agent Development and Validation Workshop) (Current)
- Mentored Duke heme/onc fellows research proposals (Frank Chen; Carey Anders)
- Served as research mentor for Dr. Gordana Vlahovic K12 award

- Currently mentoring Duke heme/onc fellow research proposals (John Piede; Will Gwin III)

Areas of research interests:

- Translational oncology research: elucidating the biological effects of targeted oncology therapies on proliferation and survival signaling networks in human epithelial tumors
- Identification of biomarkers/predictors of response to targeted cancer therapies for patient selection in clinical trials, dose/schedule optimization using biology rather than empiricism, and selection of combination therapies using targeted agents using scientific rationale
- Understanding mechanisms of primary and secondary resistance to targeted cancer agents, notably small molecule inhibitors of ErbB tyrosine kinases
- Elucidating the biological effects of combining small molecule signal transduction inhibitors with immunotherapeutic strategies, on growth and survival signaling networks in tumors
- Development of experimental cancer therapeutics
- Designing and implementing clinical strategies to develop novel targeted cancer agents in early phase clinical trials using scientific rationale and testing hypotheses generated in preclinical cancer models

External support- gifts, grants, and contracts

	PI	% Effort	Purpose	Amount	Duration
Past:					
NRSA	N. Spector	50%	Research	$ 40,000	3 yrs (1991)
Claudia- Barr Cancer Award	Adams N. Spector	50%	Research	$ 75,000	1 yr (1991)
V Foundation Career Development Award	N. Spector	100%	Research	$150,000	2 yrs (1998)

P50 CA068438-09 Breast SPORE NCI	H. Lyerly	10%	Research	$ 50,000	2 yrs (2008)
Cytokinetics (Contract)	N. Spector	1%	Research	$140,000	1 yr (2008)
P30 CA14236-31 NCI	H. Lyerly	10%	Senior Leadership	$4,355,644	5 yrs (2009)

Present:

BC083930 (DOD Breast Cancer Program)	N. Spector	10%	Research	$375,000	3 yrs (2012)
Balderacchi (Gift)	N. Spector		Research	$500,000	7/07-present
AP4 (Gift) GlaxoSmithKline	N. Spector		Research	$ 65,000	1 yr (2013)
Susan G. Komen Foundation	N. Spector	15%	Research	$1,000,000	(2010-2014)
Millennium/Takeda	N. Spector	15%	Research	$100,000	l yr (2012)
26152/9808897 UT MD Anderson	V. Seewaldt	5%	Research	$489,600	(2012-2017)
W81XWH-09-1-0065 DOD	N. Spector	15%	Research	$124,313	3 yrs (2012)
P30 CA14236-38 NCI	M. Kastan	10%	Senior Leadership	$232,985	(2009-2014)
P30 CA14236-38 NCI	M. Kastan	10%	Program Leadership	$375,174	(2009-2014)
Bayer Corporation	N. Spector	1%	Research	$108,259	1 yr (2012)
University of NC	Sin-Ho, Jung	4%	Research	$ 21,983	2 yrs (2012)
NC111085 DOD	H. Lyerly	10%	Research	$1,606,648	(2012-2017)
BC113107 DOD	H. Lyerly	15%	Research	$ 547,911	(2012-2017)

Clinical activity: Attending hematology/medical oncology fellows VA clinic one day per week

Participation in academic and administrative activities at DUMC:

- Co-director: Experimental Therapeutics (Oncology) Program
- Associate co-Director: Clinical Research, Breast Cancer Program (DCI)

ROBERT T. SARISKY, PhD, MBA

Lansdale, PA

EDUCATION

- Wharton Executive Education (non-degree classes), Philadelphia PA, 2003 – 2004
- Lehigh University, Bethlehem PA – M.B.A. Marketing, 1998 – 2001
- Johns Hopkins University, Baltimore MD – Post-Doctoral Fellowship, 1994 – 1996
- The Pennsylvania State University, Hershey PA – Ph.D. Genetics, 1989 – 1994
- University of Scranton, Scranton PA – B.S. Biology, 1985 – 1989

PROFESSIONAL EXPERIENCE

2009 – 2012	Vice President, Business Development, Oncology, JNJ PRD, Springhouse, PA
2008 – 2009	Vice President, External Research & Early Development, JNJ PRD, Yardley, PA
2006 – 2008	Senior Director, Immunology and Alliance Research, Centocor R&D, Radnor PA
2005 – 2006	Director, Immunobiology and Infectious Diseases, Centocor R&D, Radnor PA
2004 – 2005	Director, Infectious Diseases Research, Centocor R&D, Radnor PA
2003 – 2004	Associate Director, Infectious Diseases Research, Centocor R&D, Radnor PA
2003	Director Project Management, GlaxoSmithKline Pharmaceuticals, Upper Merion
2001 – 2002	Director, Virology Department, GlaxoSmithKline Pharmaceuticals, Collegeville PA
2000 – 2001	Head, Host Defense Models, GlaxoSmithKline Pharmaceuticals, Collegeville PA
2001 – 2002	AdHoc Venture Reviewer, S.R.One Limited and Euclid Partners, SmithKline Beecham Pharmaceuticals, Conshohocken PA
1999 – 2000	Senior Investigator, Molecular Virology & Host Defense Department, SmithKline Beecham Pharmaceuticals, Collegeville PA
1996 – 1999	Investigator, SmithKline Beecham Pharmaceuticals and Consumer Healthcare, Molecular Virology & Host Defense Department, Collegeville PA

TEACHING EXPERIENCE

2009 – 2011	Adjunct Lecturer Rutgers MBA program, Newark NJ
2006 – 2007	Adjunct Full Professor, Microbiology & Immunology, Drexel Univ., Philadelphia PA
2002 – 2005	Adjunct Lecturer Microbiology, Thomas Jefferson University, Philadelphia PA

SUMMARY OF EXPERIENCE

- Consumer Healthcare and Pharmaceutical industry experience with emphasis on target discovery through IND/BLA filing
- Prescription-to-OTC switch antiviral experience (Denavir & Vectavir)
- Post-marketing product support (Famvir & Remicade)
- Supplemental NDA filing antiviral experience (Penciclovir)
- Oversaw Biological License Applications (Ustekinumab/CNTO1275 and Golimumab/CNTO148)
- Managed progression of discovery research for Immunology and Infectious Disease agents
- Expertise in small molecules, biologics and technology platforms

- Business Development negotiation and contract expertise in Oncology, with strong understanding of both university and industry perspectives
- Participant in a novel open-innovation business model (eRED) to bridge funding and knowledge gap between academic and industry
- Strong skill sets and creative approaches for delivering open innovation
- Expertise in the development of strategic plans, execution at both the tactical and operational levels, and resulting performance metrics
- Established Adjunct Faculty program for Centocor PhDs at Drexel University
- Initiated External Alliance Program for Outsourcing / Off-shoring partnerships for Centocor
- Experience in providing lectures on biology, immunology, virology, drug discovery, business development and negotiation

PROFESSIONAL EXPERIENCE DETAILS

***Vice President* –** Business Development Oncology

Johnson & Johnson Pharmaceutical Services, Springhouse, PA

- Establish strategic priorities for Oncology Franchise to meet revenue goals
- Lead scientific licensing and business development transaction teams
- Serve as Chief negotiator and business case owner; lateral influence within a matrix
- Negotiate and execute broad range of WW business agreements (some public examples):
  - Mass General (CTC diagnostic platform)
  - Argenta (risk-share oncology discovery)
  - Koch Institute / MIT (Transcend RFP 5 year partnership)
  - Aveo (Ron mAb licensing)
  - Foundation Medicine (Sequencing technology application to Zytiga)
  - Forma Therapeutics (Exclusive license & option agreement in tumor metabolism)
  - Oncology Biomarker Consortia collaborative agreement (Life Technologies, Astra Zeneca, U. Oxford, Oxford Hospital Trust and UK Technology Strategy Board)
  - Univ Texas (mAb research agreement and option to license)
  - Pharmacyclics (Ph III-ready PCI-32765 compound WW licensing; 50-50 P&L split)
  - Multi-party licensing agreements between universities/industry/NFP
- Establish commercial and financial business case; secure senior executive /Board support
- Additional responsibilities include negotiation of amendments, RFPs, establishing post-doc funding agreements, securing FTO non-exclusive research licenses, Investigator-initiated and co-sponsored trial agreements
- In partnership with counsel responsibility to establish MTAs and CDAs
- Provide integral business development support for M&A and Financial analyses
- Partnering with various entities including venture capital, consortia, investment bankers, technology offices and virtual incubators, to establish creative business models
- Solicit and utilize Business Analytic and Competitive Intelligence to build business case
- Provide leadership to team of negotiators and scientific licensing professionals for supporting closure of additional deals. Some public examples below:
  - Metamark Genetics, Anchor Therapeutics, Biogen-Idec, Horizon, Merck, Astex, Proteros, NIH

***Vice President* –** External Research and Early Development

Johnson & Johnson Pharmaceuticals R&D, Inc., Yardley, PA

- Establish an external drug discovery portfolio for JNJ in partnership with universities, institutes, non-profit foundations and private biotechnology firms reporting into Bus Dev
- Build an ecosystem of alliances including innovators, CROs, funding syndicates, venture philanthropy and KOLs

- Identify, secure, incubate and manage external discovery projects within a milestone-driven project plan; assist PI's in creation of work plan
- Establish an HCC-approved scientific grants review, prioritization and funding process
- Partner closely with University Dean's, Board of Directors, Department Chairs and Principle Investigators to discuss talent, innovation and action plans
- Cultivate, solicit and steward matching gifts from a self-created network of relationships with not-for-profit institutions and foundations, securing 2-3x leverage
- Delivered steady-state portfolio of over 40 projects per year across all therapeutic areas
- Leveraged partnerships across JNJ matrix with JJDC and R&D teams

***Senior Director* –** Immunobiology and Alliance Research

Centocor, Inc., Radnor, PA

- Direct discovery research divisional areas for Innate Immunity & Microbial Pathogenesis, Autoimmunity, Fibrosis and Tissue remodeling, Allergic & Pulmonary Disorders, Infectious Diseases and Product Support for Remicade
- Built team accountable for IMID preclinical research from discovery to NME selection with focus on host pathogenesis
- Ensure on-time BLA filings for CNTO148 (Golimumab; anti-TNF) and CNTO1275 (Stelara; anti-IL12/23)
- Serve as Core Member on Therapeutic Area Optimization Committee to define commercial, clinical, regulatory activities in context of discovery strategy
- Declare and support NMEs: CNTO148, CNTO1275, CNTO888, CNTO136, CNTO1959, CNTO5825, CNTO3157
- Led Toll-Like Receptor / Innate & Adaptive Immunity focus for department
- Initiated and direct Alliance Research group responsible for target identification and validation OUS

***Director* –** Infectious Diseases Research

Centocor, Inc., Radnor, PA

- Direct Virology, Microbiology and Immunology research
- Build portfolio of therapeutics for RSV, HIV, Pulmonary Infections, GI disorders, and immune-mediated inflammatory disorders
- Established collaborative partnering with Alza, Tibotec and J&J PRD
- Initiate and manage external alliances and collaborations
- Member of Centocor Research Executive Committee
- Core member J&J Anti-Infective Working Group and Virology Therapeutic Area Optimization Committees
- Member J&J Project BioBridge and Corporate Acquisition Teams
- Budgetary responsibility
- Initiated Drexel University undergraduate co-op internship program at Centocor
- Initiated Adjunct Faculty Program for Centocor staff at local universities
- Member of Bridge to Employment and College Recruiting Teams
- Champion offshore ventures for target identification and target validation

***Associate Director* –** Infectious Diseases Research
Centocor, Inc., Radnor, PA

- Lead biopharmaceutical drug-discovery department for serious infectious diseases
- Direct Virology and Immunology research activities on RSV, HIV and innate immunity

- Develop franchise of New Molecular Entities to stimulate host immunity and inhibit the pathogen virulence
- Establish strategic direction for Infectious Diseases within Cencotor
- Initiate collaborative partnering across Johnson & Johnson Pharmaceutical divisions
- Establish external alliances and collaborations
- Core member of Therapeutic Area Commercial Team for Infectious Diseases
- Centocor Research Executive Committee member to direct and manage the Biology Research portfolio
- Chair, Centocor Discovery Research Safety Committee

Director – Project Management, Cardiovascular Diseases CEDD

GlaxoSmithKline Pharmaceuticals, Upper Merion, PA

- Responsible for management of compound development team activities, GANNT chart mapping and proactive issue identification /resolution

Director – Virology Department, Metabolic & Viral Diseases CEDD

GlaxoSmithKline Pharmaceuticals, Collegeville, PA

- Develop and implement Discovery Strategy for antivirals and immunomodulators
- Direct and progress HCV Antiviral Discovery Programs from screening hit to toxicology screening
- Championed establishment of interferon and immuno-modulation programs for viral infection and oncology
- Research Management Committee Board member for external alliance on HCV antivirals
- IND report preparation to support FDA filing of NCEs
- Member Biology Leadership Team for management of discovery research
- Establish and manage external research collaborations and alliances

Head– Host Defense Models, Antimicrobial & Host Defense CEDD

GlaxoSmithKline Pharmaceuticals, Collegeville, PA

- Provide leadership and develop portfolio strategy for Host Defense
- Liaise and manage cross-CEDD discovery functions
- Establish strategic alliance / partnerships / in-licensing
- Champion Hepatitis C Virus Drug Discovery matrix team
- Responsible for line managing 20 research scientists
- Initiate novel drug discovery screening campaigns on host defense against infectious disease
- Manage and direct external collaborations and alliances

Ad Hoc Venture Reviewer

SR One, SmithKline Beecham Venture Capital Group, Conshohocken, PA

- Provide technical and business strategy assessment of venture capital opportunities

Senior Investigator– Molecular Virology & Host Defense

SmithKlineBeecham Pharmaceuticals, Collegeville, PA

- Champion Hepatitis C Virus Drug Discovery matrix teams
- Establish strategic alliances and evaluate in-licensing opportunities for therapeutic area
- Develop and train 13 scientists for Infectious Disease Drug Discovery programs (HCV, HPV, HIV, HBV)

Investigator– Molecular Virology & Host Defense and Consumer Healthcare

SmithKlineBeecham Pharmaceuticals, Collegeville, PA

- Consumer Healthcare-funded position in Pharma sector to lead and develop research program on antiviral resistance for human herpesviruses
- Develop and train 8 scientists
- Perform and direct research on marketed antiviral agent (Denavir, Vectavir) to support sNDA submissions and prescription-to-OTC switch
- Preparation of documents for FDA filings and participate in FDA review meetings
- Provide response to FDA for antiviral resistance issues
- Develop susceptibility testing strategy for 11 worldwide clinical trials
- Established international guidelines for NCCLS antiviral testing
- Deliver training to Consumer Healthcare Sales Staff (Pittsburgh)

Post-Doctoral Fellow– Department Pharmacology & Molecular Sciences

Johns Hopkins School of Medicine, Baltimore MD

- Research Projects: Analysis of Human Cytomegalovirus and Eptstein-Barr Virus mechanisms of DNA replication.
- Recipient Amercian Cancer Society Fellowship

Research Internship– Department of Immunology

Connaught Laboratories, Swiftwater PA

- Research Projects: Purification and characterization of iron binding proteins of *N. meningitis*

ADDITIONAL ACTIVITIES

- NCI SBIR Development Center Investor Forum Grant Reviewer 2011-12
- Member University of Miami Innovation Corporate Advisory Council and Johns Hopkins Alliance for Science and Technology Development 2008 - 2010
- Editorial Board Member, Recent Patents CNS Drug Discovery, Jan 2008 – 2010
- University of Michigan Medical School Partnership Forum Panel Board Member – Enhancing Relationships with Industry. October 2007.
- Member University Pennsylvania Executive Team: Med into Grad Initiative from Howard Hughes Medical Institute for integrating medical knowledge into graduate training, 2006 – 2009
- Editorial Board Member, Recent Patent Reviews on Anti-Infective Drug Discovery, 2005 – 2009
- Board of Trustees, Delaware Valley Science Institute, 2003 – 2007
- Chair, Marketing and Public Relations, Delaware Valley Science Institute, 2005 – 2007
- Chair, NIH/NIAID Antiviral Grants and Contracts Review Committee, 2003.
- NIH/NIAID Emerging Infectious Diseases and Biodefense Grants Review Committee Member, 2004

- Ad Hoc Reviewer, Journal of Virology, Virus Research, Clinical Microbiology and Infectious Diseases, Hepatology, Antiviral Research, Antiviral Agents and Chemotherapy, Molecular Cancer Therapeutics, 2003 – 2007
- Champion SmithKline Beecham Visiting Scientist Program, Philadelphia Area School System, 1998 – 2002
- Lead Presenter, SmithKline Beecham, Take Your Child To Work Day, Hands-on Science Workshops, 1997 – 2002
- Annual Delaware Valley Science Fair Judge, 1997 – Present.
- Education Outreach Science Workshop Presenter, PA High Schools, 1996 – 1998
- Science Mentor, Boston Museum of Scientific Discovery, 1997 – 1999
- Teaching Assistant, Genetic Engineering Course, University of Scranton, Scranton PA, 1989

AWARDS AND HONORS

2011	Global Leadership Award
2008	Johnson & Johnson Platinum Award
2007	Johnson & Johnson Standards of Leadership Award
2005	J&J STAR Award – HCV Core Team Strategy Leader
2004	Centocor Crystal Impact Award
2004	Recipient Governor's Safety Award
2003	Award recipient competitive COSAT J&J research grant
2003	Johnson & Johnson Standards of Leadership Award
2002	Silver Impact Award, GlaxoSmithKline
1997 – 2001	5 Consecutive Merit Ratings of 1.0 (Exceeds Expectations)
2001	Team Impact Award, SmithKline Beecham
1999	Silver Impact Award, SmithKline Beecham
1998	Discretionary Stock Award, SmithKline Beecham
1997	Silver Impact Award, SmithKline Beecham
1995 – 1996	American Cancer Society Postdoctoral Fellowship Recipient, Johns Hopkins University School of Medicine
1993	Pre-doctoral Fellowship, Genetics Program, Department of Microbiology and Immunology, Pennsylvania State University
1991	First Place Oral Presentation, Fourth Annual Research Forum, PSU
1989	B.S. *Magna Cum Laude*, University of Scranton
1988	Alpha Sigma Nu Honor Society, University of Scranton
1985 – 1989	Presidential III, Gunster and J.T. Endowment Scholarships, University of Scranton

PROFESSIONAL AFFILIATIONS

- American Society of Microbiology
- American Society for Virology
- Infectious Diseases Society of America
- American Thoracic Society

PUBLICATIONS

1. **Sarisky, R.T.** and P.C. Weber. Requirement for double-strand breaks but not for specific DNA sequences in herpes simplex virus type 1 genome isomerization events. Journal of Virology, **68**: 34-47, (**1994**).

2. **Sarisky, R.T.** and P.C. Weber. Role of anisomorphic DNA conformations in the negative regulation of a herpes simplex virus type 1 promoter. Virology, **204**: 569-579, (**1994**).

3. Martinez, R. **Sarisky, R.T.**, Weber, P.C. and S.K. Weller. Herpes simplex virus type 1 alkaline nuclease is required for efficient processing of viral DNA replication intermediates. Journal of Virology, **70**: 2075-2085, (**1996**).

4. **Sarisky, R.T.** and G.S. Hayward. Evidence that the UL84 gene product of human cytomegalovirus is essential for promoting oriLyt-dependent DNA replication and formation of replication compartments in co-transfection assays. Journal of Virology, **70**:7398-7413, (**1996**).

5. **Sarisky, R.T**., Gao, Z., Liberman, P.L., Fixman, E.D., Hayward, G.S. and S.D. Hayward. Evidence for a replication function associated with the activation domain of the Epstein-Barr virus Zta transactivator. Journal of Virology, **70**: 8340-8347, (**1996**).

6. Semmes,O.J., **Sarisky, R.T.**, Gao,Z., Zhong,L., and S.D. Hayward. Mta has properties of an RNA export protein and increases cytoplasmic accumulation of Epstein-Barr Virus Replication gene mRNA. Journal of Virology **72**: 9526-9534, (**1998**).

7. Nicholas, J., Zong, J.C., Alcendor, D.J., Ciufo, D.M., Poole, L.J., **Sarisky, R.T.**, Chiou, C.J., Zhang, X., Wan, X., Guo, H.G., Reitz, M.S., Hayward, G.S. Novel organizational features, captured cellular genes, and strain variability within the genome of KSHV/HHV8. Journal National Cancer Institute Monograph **23**: 79-88, (**1998**).

8. **Sarisky, R.T.**, Nguyen, T.T., Duffy, K.E., Wittrock, R.J. and J.J. Leary. Difference in incidence of spontaneous mutations between herpes simplex virus types 1 and 2. Antimicrobial Agents and Chemotherapy **44**: 1524-1529, (**2000**).

9. **Sarisky, R.T.**, Quail, M., Clark, P., Nguyen, T.T., Wittrock, R., Bartus, J., Halsey, W., Van Horn, M., Sathe, G., Van Horn, S., Kelly, M., Bacon, T. and J. Leary. Characterization of herpes simplex virus isolates selected in culture for resistance to penciclovir or acyclovir. Journal of Virology **75**: 1761-69, (**2001**).

10. Ranjith-Kumar, C.T., Gajewski, J., Gutshall, L., Maley, D., **Sarisky, R.T.** and C.C. Kao. Terminal nucleotidyl transferase activity of recombinant flaviviridae RNA-dependent RNA polymerases: implication for viral RNA synthesis. Journal of Virology **75**: 8615-8623 (**2001**).

11. **Sarisky, R.T.** Differential selection of drug-resistant herpes simplex virus in culture between acyclovir and penciclovir. International Antiviral News **9**: 104-107 (**2001**).

12. Levin, M.J., Weinberg, A., Leary, J. and **R.T. Sarisky**. Development of acyclovir-resistant herpes simplex virus during the early treatment of herpes neonatorum. Pediatrics Infectious Disease Journal **20**: 1094-1097 (**2001**).

13. **Sarisky, R.T.**, Crosson, P., Cano, R., Quail, M., Nguyen, T.T., Wittrock, R.J., Clark, P., Bacon, T.H., Hodinka, R.L., Sacks, S.S., Caspers-Velu, L. and J. Leary. Comparison of methods for identifying resistant herpes simplex virus and measuring antiviral susceptibility. Journal of Clinical Virology **23**: 191-200 (**2001**).

14. **Sarisky, R.T.**, Cano, R., Nguyen, T.T., Wittrock, R.J., Duffy, K.E., Clark, P., O'Leary, Bacon, T. Caspsers-Velu, Hodinka, R.L. and J. Leary. Biochemical characterization of a virus isolate from

a patient with herpes keratitis clinically-resistant to acyclovir. Clinical Infectious Diseases **33**: 2034-2039 (**2001**).

15. **Sarisky, R.T.**, Bartus, H.R., Dennis, S.A., Quail, M.R., Nguyen, T.T., Wittrock, R.J., Halsey, W.S., Bacon, T.H., Leary, J.J. and D. Sutton. Absence of rapid selection for acyclovir or penciclovir resistance following suboptimal prodrug therapy of HSV-infected mice. BioMed Central Infectious Diseases, **1**: 24-32, (**2001**).

16. Leary, J., Wittrock, R., **Sarisky, R.T.**, Weinberg, A. and M. Levin. Comparative susceptibility of herpes simplex viruses to penciclovir and acyclovir in eight cell lines. Antiviral Agents and Chemotherapy **46**: 762-768 (**2002**).

17. Duffy, K., Quail, M., Nguyen, T.T., Wittrock, R.J., Halsey, W., Leary, J. and **R.T. Sarisky**. Assessing the contribution of the herpes simplex virus DNA polymerase to replication fidelity using polymerase-recombinant viruses. BioMed Central Infectious Diseases **2**:7 (**2002**).

18. **Sarisky, R.T.**, Bacon, T.H., Boon, R., Locke, L., Nguyen, T.T., Leary, J., Esser, K. and R. Saltzman. Penciclovir susceptibilities of herpes simplex virus type 1 isolates from patients using penciclovir cream for the treatment of recurrent herpes labialis. Antimicrobial Agents and Chemotherapy **46**: 2848-2853 (**2002**).

19. Dhanak, D., Duffy, K.J., Johnston,V., Lin-Goerke, J., Darcy, M., Shaw, A., Silverman, C., Earnshaw, D.L., Casper, D.J., Baker, A., Gutshall, L., Maley, D., Gates, A., Macarron, R., Delvecchio, A., Hoffman, G., Keenan, R. and **R.T. Sarisky**. Identification and biological characterization of novel, small molecule inhibitors of the hepatitis C virus RNA-dependent RNA polymerase. Journal of Biological Chemistry **277**:38322-38327, (**2002**).

20. Ranjith-Kumar, C.T., Gutshall, L., Kim, M-J., **Sarisky, R.T.**, and C.C. Kao. Requirements for de novo initiation of RNA synthesis by recombinant Flaviviridae RNA-dependent RNA polymerase. Journal of Virology **76**:12526-12536 (**2002**).

21. Ranjith-Kumar, C.T., Kim, Y-J., Gutshall, L., Silverman, C., Khandekar, S., **Sarisky, R.T.** and C.C. Kao. Mechanism of de novo initiation by the hepatitis C virus RNA-dependent RNA polymerase: role of divalent metals. Journal of Virology **76**:12515-12525 (**2002**).

22. Bacon, T.H., Levin, M.J., Leary, J., **Sarisky, R.T.** and D. Sutton. Herpes simplex virus resistance to acyclovir and penciclovir after two decades of antiviral therapy. Clinical Microbiology Reviews, **16**:114-128, (**2003**).

23. Bacon, T.H., Locke, L., Nguyen, T.T., Duffy, K., Boon, R., Quail, M.R., Leary, J., Esser, K.M, Saltzman, R. and **R.T. Sarisky**. Profiling penciclovir susceptibility and prevalence of resistance of herpes simplex virus isolates across eleven clinical trials. Archives of Virology **148**:1757-1769, (**2003**).

24. Gu, B., Johnston, V., Gutshall, L., Nguyen, T., Gontarek, R.R., Darcy, M.G., Tedesco, R., Dhanak, D., Duffy, K.J., Kao, C.C. and **R.T. Sarisky**. Arresting initiation of HCV RNA synthesis using heterocyclic derivatives. Journal of Biological Chemistry **278**:16602-16607 (**2003**).

25. Gu, B., Gates, A.T., Isken, O., Behrens, S.E. and **R.T. Sarisky**. Replication studies using a genotype 1a subgenomic HCV replicons. Journal of Virology **77**:5352-5359, (**2003**).

26. DeMarini, D., Johnston, V., Konduri, M., Gutshall, L. and **R.T. Sarisky**. Intracellular RNA-dependent RNA polymerase activity. Journal of Virological Methods **113**:65-68, (**2003**).

27. Ranjith-Kumar, C.T., Santos, J.L., Gutshall, L, Johnston, V., Lin-Goerke, J., Kim, M.J., Porter, D., Maley, D., Greenwood, C., Earnshaw, D.L., Baker, A., Gu, B., Silverman, C., **R.T. Sarisky** and C.C. Kao. Enzymatic activities of the GB-virus B RNA-dependent RNA polymerase. Virology **312**:270-280, (**2003**).

28. Ranjith-Kumar, C.T., Gutshall, L., **Sarisky, R.T.** and C.C. Kao. Multiple interactions within the hepatitis C virus RNA polymerase that repress primer-dependent RNA synthesis. Journal of Molecular Biology **330**:675-685, (**2003**).

29. Nguyen, T., Gates, A.T., Gutshall, L., Johnston, V., Gu, B., Duffy, K. and **R.T. Sarisky**. Resistance profile of an HCV RNA-dependent RNA polymerase Benzothiadiazine inhibitor. Antimicrobial Agents and Chemotherapy **47**:3525-3530, (**2003**).

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34. CEN5242USNP: TLR3 antagonists. October 2009.
35. WO2010040054A2. Methods for Suppressing Toll-Like Receptor Activity. April 8, 2010.
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INVENTION DISLCOSURES

1. Invention Disclosure (CID 111). Use of anti-TLR3 monoclonal antibodies as vaccine adjuvant. July **2003**.
2. Invention Disclosure (CID 110). Targeted delivery of anti-infective agents selectively to pathogen-infected cells, a bacterial cell localized areas of infection using particle-bound antigen-specific antibodies. July **2003**.
3. Invention Disclosure (CID126). Nucleic acid vaccine for respiratory syncytial virus. November **2003**.
4. Invention Disclosure (CID149). Cloning and characterization of 101F, a potent neutralizing antibody directed against the F protein of human respiratory syncytial virus. June **2004**.
5. Invention Disclosure (CID 153). Use of anti-Toll like receptor 3 agonist monoclonal antibodies for the prevention or treatment of autoimmune and inflammatory diseases. July **2004**.

6. Invention Disclosure (CID 155). Use of Toll-like receptor 3 antagonist monoclonal for the treatment and prevention of irritable bowel diseases. July **2004**.
7. Invention Disclosure (CID 162). Use of TLR3 antagonist monoclonal for the prevention or treatment of pathogen-associated lethal shock and systemic inflammatory response syndrome. August **2004**.
8. Invention Disclosure (CID 167). Use of RSV F protein derived peptides or nucleic acids encoding these peptides as a vaccine to induce protective RSV neutralizing antibodies. October **2004**.
9. Invention Disclosure (CID 169). Targeted delivery of liposomes containing anti-HIV agents to HIV-infected cells using HIV-specific antibodies, antibody related molecules, peptides, or compounds bound or coated onto the surface of a liposome. November **2004**.
10. Invention Disclosure (CID 170). Improved treatment for tuberculosis and similar granulomatous pathogens. August **2004**.
11. Invention Disclosure (CID 188). Toll like receptor signaling modulators for regulation of cell proliferation. June **2005**.
12. Invention Disclosure. Killer toxin: strategies for use in prophylaxis and therapeutics against a broad spectrum of microbial pathogens. May **2005**.
13. Invention Disclosure (CID 277): Potentiation of Interferon-Alpha Production by a Plasmacytoid Dendritic Cell-enriched Population using an anti-Toll-Like Receptor 3 Monoclonal Antibody. October **2006**.
14. Invention Disclosure (CID 292): Anti-CXCL13 and Anti-TNFa monoclonal antibodies inhibit autoimmune responses in a murine model of systemic lupus erythematosus. March **2007**.
15. Invention Disclosure (CID 292): CXCL13 antagonists and their use for the treatment of inflammatory diseases. March **2007**.
16. Invention Disclosure (CID 297): Use of single-stranded DNA oligonucleotides to antagonize TLR signaling. April **2007**.
17. Invention Disclosure: TLR3 as a target for acute lung injury and fibroproliferative disorders. October **2007**.
18. Invention Disclosure (CID 344): Human anti-TLR3 monoclonal antibodies, compositions and activity. February **2008**.
19. Invention Disclosure (CID 345): Signaling-deficient TLR3 isoform. February **2008**.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE CHAIR PETE GEREN**
From:	**WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
Subject:	**SECTION 102.1062 WAIVER – DR. JOHN**
Date:	**HELLERSTEDT JANUARY 14, 2016**

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2016 for Program Integration Committee (PIC) member DSHS Commissioner Dr. John Hellerstedt, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Commissioner Hellerstedt to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background

Dr. Hellerstedt was appointed Commissioner of the Department of State Health Services (DSHS) on January 1, 2016. The DSHS Commissioner is a statutorily designated member of the PIC. As a PIC member, Commissioner Hellerstedt is called upon to exercise discretion related to whether applications proposed for grant awards by the peer review committees should be recommended to the Oversight Committee for final approval.

DSHS is a CPRIT grant recipient, which implicates conflict of interest concerns. Health & Safety Code Section 102.106(c)(3) mandates that a professional conflict of interest exists if a PIC member is an employee of an entity applying to receive or receiving CPRIT funds. Furthermore, CPRIT's administrative rule 702.13(c) categorizes this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the Section 702.13(c) "super conflict" category must be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted..."

CPRIT's administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Commissioner Hellerstedt's Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. Commissioner Hellerstedt's participation in the review process is compelled by the statute. In order to fulfill legislative intent that the DSHS Commissioner serve as a PIC member, the proposed waiver must be granted. The proposed limitations will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that Commissioner Hellerstedt be permitted to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. Attend and participate fully in the PIC meetings except that Commissioner Hellerstedt shall not participate in the PIC's discussion or vote on grant award recommendations to be made to DSHS;
2. Have access to grant application information developed during the grant review process, except for information related to DSHS applicants, if any; and
3. Provide information to the Oversight Committee or CPRIT personnel about the grant review process and applications recommended by the PIC for grant awards, including answering questions raised by the Oversight Committee or CPRIT personnel. To the extent that information is provided by Commissioner Hellerstedt on his own initiative in a review cycle in which DSHS is a grant applicant, the information provided by Commissioner Hellerstedt should be general information related to the overall grant application process and not advocate specifically for a grant application submitted by DSHS.

CPRIT's Compliance Officer is statutorily required to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation. The Compliance Officer shall report to the Oversight Committee any violation of this waiver prior to the Oversight Committee's action on the PIC recommendations.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Commissioner Hellerstedt has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Commissioner Hellerstedt will follow the required notification and recusal process.

Pursuant to Texas Administrative Code Section 701.13(7), the Advisory Committee on Childhood Cancers (ACCC) is required to report at least annually to the Oversight Committee regarding the activities of the Committee. In addition to the written report submitted to the Oversight Committee, Dr. Susan Blaney, will give a presentation to the Oversight Committee.

2015 Annual Report
CPRIT Advisory Committee on Childhood Cancer (ACCC)
Submitted to the CPRIT Oversight Committee
February 2016

I. Introduction

The CPRIT Advisory Committee on Childhood Cancer (ACCC) convened on November 9, 2015 with prior and subsequent discussions by email and teleconferences to review progress as well as to formulate recommendations to the CPRIT Oversight Committee on priority areas for funding of research, prevention/survivorship, and product development in childhood cancer.

The ACCC as well as the pediatric cancer research and advocacy committees are grateful to CPRIT for its ongoing focus on research excellence as guided by the peer-review process. We specifically applaud the opportunities that have been provided for funding of research in childhood and adolescent cancer by CPRIT, particularly the RFAs specifically requesting grant applications focused on these cancers. The peer-reviewed funding provided for high-impact research pediatric and adolescent cancer research, including the funded initiatives in prevention and product development, will ultimately lead to advances that will positively improve the lives and long term outcome of children with cancer in Texas as well as across the world.

II. Progress to date

Under the leadership of Dr. Kripke, the success of CPRIT research applications focused on childhood cancer has risen substantially. This success is in large part due to focused RFA mechanisms that have resulted in the funding of more than 30 childhood and cancer research projects to date. Specifically, an increase has been noted in the number of grants devoted to childhood and adolescent cancers (from 4 percent to 13 percent), prevention and early detection (13 percent to 17 percent), and computational biology (2 percent to 4 percent). We anticipate that these numbers will continue to increase with the release of targeted RFAs devoted to these priority areas. This impact is tremendous since the life years impacted by survivors of childhood cancer greatly exceeds that of adult cancer survivors.

Further evidence of this success is measured by publications and new grant dollars. Although the impact in this regard will take an additional three to five years to mature, at this early juncture there have been more than sixty-five peer review publications, with numerous others in progress, that have emanated from these CPRIT-funded pediatric-focused research projects. These include publications in high impact journals such as *Journal of*

Clinical Oncology, Blood, Nature Reviews, and Nature Communications. Additionally, these CPRIT-funded investigators have already been able to garner an additional $10 million dollars in peer review funding to support the pursuit of their important research initiatives that are focused on pediatric cancer research.

The CPRIT-funded research initiatives focused on pediatric cancer are quite diverse and range from prevention strategies through survivorship. The majority of funded awards have been Individual Investigator Research Awards (IIRA); however, there are also two funded Multi-Investigator Research Awards (MIRAs) including one focused on osteosarcoma and another focused on soft tissue sarcomas

III. The ACCC recommends that current strengths in the CPRIT Research Portfolio remain a high priority:

1) Investigator-Initiated Research

Support for clinical and translational research carried out by individual investigators or collaborative teams of investigators should remain a high-priority.

ACCC Recommendations

a. The CPRIT RFA for individual investigator grants specific to childhood and adolescent cancer, similar to RFA R-15-IIRACCA-1, should be issued on a continuous basis.

b. Release of an RFA for multi-investigator research awards (MIRAs) focused on childhood and adolescent cancer (with an emphasis on inter-institutional collaboration) is recommended.

c. Increasing the number of pediatric oncologists and laboratory investigators that serve on CPRIT grant review panels is recommended.

2) Recruitment Awards

The recruitment award program has been successful in bringing high quality investigators to Texas. However, relatively few investigators trained in childhood cancer basic, translational or clinical have been brought to Texas by the recruitment grants.

ACCC Recommendations

a. Consideration should be given to setting aside at least one recruitment grant for pediatric oncology for each recruitment RFA (First Time, Tenure Track Faculty Members; Rising Stars, and Established Investigators). As review committees are currently constituted it is likely that the preponderance of adult oncology reviewers on the committees may preferentially select for researchers in adult oncology, as they may not be sufficiently familiar with pediatric cancer research or research leaders.

b. Consideration should be given to prioritizing recruitment of suitable candidates to underserved areas of Texas as long as the appropriate research or clinical resources are available in those areas.

3) Core Facility Grants

The ACCC recommends that CPRIT develop additional initiatives for core facilities to support childhood cancer

a. **Pediatric Cancer Research Cores**. Continuation of the opportunity for institutions to submit an application for a shared resource to support research directed toward childhood and adolescent cancer in addition to an additional application to support another area of research (e.g., RFA R-16-CFSA-2)

b. **Multi-institutional core resource grants to support childhood cancer research.** The ACCC recommends that CPRIT consider developing a grant funding mechanism to support the development high-impact, multi-institutional shared resources that support childhood cancer research in Texas such as preclinical drug testing and/or model development cores, research or clinical (CLIA-certified) sequencing cores that define the genomic alterations in childhood cancers to more rapidly advance the field of precision medicine in pediatric oncology.

IV. Prevention Portfolio

Prevention initiatives in childhood and adolescent cancers

With the increased survival rates of childhood cancer, issues related to survivorship including long-term side effects of treatment, quality of life, fertility, employment and a host of other concerns have become increasingly prominent. The number of years of life saved by successfully treating a child with cancer is substantially greater than that of an adult, which magnifies the importance of survivorship issues. We suggest that CPRIT continue

to support prevention initiatives relating to childhood cancer survivorship. In addition, it has recently become evident that a significant number of childhood cancers are related to cancer pre-disposition syndromes. We encourage CPRIT to support research and prevention services targeting patients at high risk of initial and secondary cancers.

V. Product Development Portfolio

Commercial Development of Diagnostics and Therapeutics for Childhood Cancer

We appreciate CPRIT's recognition of and commitment to product development efforts that will support advances in childhood, as well as adult, cancers (DP140034, DP150094, and DP150083). Nevertheless, a paucity of pediatric cancer drug development programs exist in the pharmaceutical industry. Additionally, none of the commercial entities currently funded by CPRIT have active clinical trials of diagnostics or therapeutics in childhood cancer.

The ACCC recommends:

Exploration of innovative ways to facilitate and encourage commercial development of drugs and diagnostics for childhood cancer is recommended. A suggested first step would be to convene a working group of interested stakeholders (including pediatric oncologists, pediatric oncology patient advocates, CPRIT Product Development leadership/reviewers, and CPRIT-funded commercial entities). This working group could define the barriers facing commercial development of drugs and diagnostics for childhood cancer and develop recommendations for approaches to overcome the identified barriers. Development of a mechanism for prioritizing and accelerating funding considerations to facilitate development of investigational agents with demonstrated clinical activity in children with cancer is suggested.

VI. Summary

The ACCC is grateful to CPRIT for its commitment to prioritizing and funding groundbreaking cancer research and prevention programs that are focused on childhood cancer. This commitment will have a profound impact for children with cancer and their families both locally and globally.

Pursuant to Texas Administrative Code Section 701.13(7), the University Advisory Committee (UAC) is required to report at least annually to the Oversight Committee regarding the activities of the Committee. In addition to the written report submitted to the Oversight Committee, Dr. Cheryl Lyn Walker and Dr. Mary Ann Ottinger, Chair and Vice-Chair of the UAC, will give a presentation to the Oversight Committee.

2015 CPRIT University Advisory Committee Annual Report
Submitted to the CPRIT Oversight Committee
Jan 31, 2016

CPRIT 2015 UAC Membership

Cheryl Lyn Walker, Ph.D.
Chair 2014-2016
Director
Institute of Biosciences and Technology
Texas A&M University

Mary Ann Ottinger, Ph.D., Vice-Chair
Chair, 2016-2018
Associate Vice Chancellor for Research
University of Houston System

P. Michael Conn, Ph.D.
Senior Vice President for Research/Associate Provost
Texas Tech Health Sciences Center

Billy C. Covington, Ph.D.
Associate Vice President for Research
Texas State University

Mike Jacobson, Ph.D.
Founding Dean
College of Pharmacy
University of North Texas Health Science Center at Fort Worth

C. Kent Osborne, M.D.
Director
Duncan Cancer Center
Baylor College of Medicine

Yousif Shamoo, Ph.D.
Vice Provost for Research
Rice University

Ian Thompson, M.D.
Professor
Director, Cancer Therapy and Research Center
University of Texas Health Science Center at San Antonio

James Willson, M.D.
Associate Dean, Oncology Programs
Director, Harold C. Simmons Cancer Center
University of Texas Southwestern Medical Center

2015 UAC Meetings and Teleconferences

February 5, 2015
May 11, 2015
August 21, 2015
October 19, 2015
November 10, 2015

During 2015, the UAC met approximately quarterly to receive updates and review CPRIT initiatives, provide input to the Chief Scientific Officer, Dr. Kripke, and develop recommendations to the CPRIT Oversight Committee to enhance effectiveness and impact of the CPRIT grant program. While in 2014 UAC discussions focused on CPRIT Program Priorities (provided to the Oversight Committee in a White Paper and the 2014 Annual Report), in 2015 the Committee focused their discussions on developing recommendations for CPRIT to address outcome metrics that reflect the accomplishments and contributions of the CPRIT funded research. A summary of UAC discussions and recommendations follows:

1. UAC Perspective on 2015 CPRIT Initiatives

- Recruitment grants and investigator-initiated research awards continue to be highly successful programs for CPRIT. Given the importance, and widespread appreciation of the impact of Recruitment grants, the amount of funds being invested in these recruitment awards is highly endorsed by UAC members. Since the CPRIT Oversight Committee now has the leeway to defer other research awards until the next fiscal year to ensure that there are sufficient funds available to make recruitment awards late in the year, the UAC does not at this time recommend CPRIT implement mechanisms to earmark funds for recruitment awards.

- The UAC applauds the issuing of RFAs in the areas of Childhood Cancer, Prevention and Computational Biology, in line with the recommendations on program priorities identified in the 2014 UAC Whitepaper. The receipt of over 50 applications in response to the call for Computational Biology grants points to the enthusiastic response of the cancer research community to this new direction.

- While MIRAs continue to be regarded as an important mechanism for promoting collaborative, interdisciplinary research, the poor success rate for funding of MIRAs in the previous round prompted new bi-directional communication between CPRIT and the state's cancer research community. The UAC recognizes and commends CPRIT's efforts in this regard, which included holding a stakeholder workshop in which ~90 investigators participated on-site and > 265 by phone. Changes to the application process were made in response to input from the community, such as increasing page lengths for some sections, and more lead time to develop proposals. This type of responsiveness to the community demonstrates CPRITs ongoing commitment not only to move the cancer research agenda forward, but also to support the Texas cancer research community by being open and receptive to community input on how to best meet this goal.

- Similarly, the low success rates for the Computational Biology grants pointed to the need to open a channel for communication with investigators in this research area. A number of specific issues that contributed to the low funding rate for these grants were identified, including lack of validation plan (and concern about sufficient funds being available to do validation studies), and the absence of biology expertise in the proposals, all of which needed to be communicated to applicants. Again, CPRIT leadership provided a highly responsive and constructive response by organizing the CPRIT Scientific Research Office Information Session on the Individual Investigator Research Awards for Computational Biology (IIRACB) Grant Program. During the session, CPRIT staff provided an overview of the grant mechanism and review criteria and presented feedback from the peer review meetings at which these applications were reviewed. Following the overview, there were opportunities for previous and future applicants to provide feedback to CPRIT regarding this mechanism and for potential applicants to ask questions. The UAC is deeply appreciative of this continuing commitment on CPRIT's part to engage the cancer research community in improving applications and increasing proposal quality and funding rates.

- Over the past year, the UAC discussed several ideas to engage in effective outreach to stakeholders, including sponsoring a CPRIT "roadshow" at universities across the state that would publicize local CPRIT investments, research success stories and impact on the citizens of Texas. San Antonio/Austin, Houston/Galveston, Lubbock and DFW were thought to be excellent regional candidates for this type of outreach activity. UAC members from those regions were enthusiastic about participating in such an effort if it were launched. To have the most impact, this effort should consist of coordinated newsfeeds from participating institutions, involving patient advocates, with precise and consistent messaging. A coordinated effort between the Chief Prevention and Communications Officer, Communication Specialist(s), and the UAC is recommended to explore the possibility of initiating such an outreach effort.

2. UAC Recommendations for Developing CPRIT Outcome Metrics

CPRIT is in the process of a self-study to identify outcome metrics to evaluate (and promote) the successes of its investments in cancer research. However, no database is currently maintained that acquires queryable publication (or other) outcome metrics. Various approaches were discussed, including those that would take advantage of 'internet crawlers' to mine the vast array of available information. Such a database if established and linked to PubMed via PMCID identifiers, could be used to provide much needed data, that could include (in addition to numbers of publications) measures of publication impact such as numbers of citations, press releases, media pickups etc. The Committee also appreciates that there is a need to educate stakeholders about what is the most exciting research going on in the community, how discoveries are being translated into clinical impact, and the tremendous impact CPRIT has had on cancer research in the state, nation and world.

<u>UAC Recommendations</u>

As a result, the UAC recommends the following be considered in the development of outcome metrics to evaluate the success of CPRIT programs, inform and educate stakeholders, and frame discussions of CPRIT's return on investment and how to apportion funds into various CPRIT programs, for example investments into academic research vs. product development programs.

General Metrics

- Publications and associated metrics (number, citations, impact factor of journal etc.) including lay explanations of why the research conducted was important
- Total cancer related grant support before and after CPRIT. For example, when NCI designation was first sought in 2006 by Baylor College of Medicine, they had $99M in total cancer relevant funding, now they have $158M. CPRIT helped directly and indirectly by bringing in successful recruits to grow programs, etc.
- Economic impact on Texas of CPRIT dollars. An example of this type of assessment can be found at http://www.unitedformedicalresearch.com/state-by-state/documents/texas.pdf. Our universities routinely calculate this type of economic impact and it always demonstrates a huge ROI multiplier. This analysis could be performed for CPRIT by a trainee with one of the Texas business schools, or under a service contract.
- Number of new jobs supported by CPRIT grants
- Success of trainees supported by CPRIT (number, recognition and awards etc.) from both training grants and research awards that support trainees in the lab. It is also important to frame this activity as growing leaders and workforce of tomorrow in Texas.

- New NCI Comprehensive Cancer Center designations that were helped significantly by CPRIT and, in some cases, happened in record time due to CPRIT support (i.e. Baylor College of Medicine and UT-Southwestern).
- New grants directly tied to support received from CPRIT
- Contribution to rankings of Texas universities (AAU membership, Tier 1 status etc.)
- Other recognition (news releases related to CPRIT-linked outcomes, recognition of Texas by community outside of state for its cancer-related research mission).

Translational Research and Product Development Metrics

- Number of new drugs developed by CPRIT now in clinic.
- Clinical trials of new treatments based on CPRIT funded work.
- Numbers of new start-ups in Texas supported by CPRIT
- Number of jobs created by Product Development program and funding new startups.

Recruitment Award Metrics

- Numbers of CPRIT Scholars and size of enterprise they have built in Texas (jobs, spin-off companies etc).
- Non CPRIT grants obtained by CPRIT Scholars after they came to TX (i.e. new money brought into the state).
- Prestigious honors and awards received by Scholars after coming to Texas (i.e. Lasker).

3. UAC Recommendations for Supporting Clinical Trials Research

Researchers face many obstacles in translating research advances to the clinic. Funding for clinical trials, or for correlative science attached to clinical trials, is difficult to acquire. Sometimes industry pays for the clinical trial but usually not the correlative science or vice versa. Many times industry pays for neither but only supplies the experimental drug to use in the trials. In the era of targeted therapy it is extremely important to be certain that new agents hit their targets, and to determine mechanisms of sensitivity, resistance and action. Furthermore, it is increasingly recognized that combinations of targeting agents will be required for optimal effects, for example combinations where one agent targets the main driver of the cancer and the other agent targets a compensatory pathway.

<u>UAC Recommendations</u>

UAC recommends that CPRIT consider specific mechanisms for funding early phase clinical trials accompanied by tissue acquisition for biological studies to obtain mechanistic insights or biomarkers that might predict response or sensitivity to the treatment. These would largely be small Phase 2 trials with tissue biopsy or blood, or completed clinical trials on which tissue has been collected and funding is needed for genomics/proteomics/metabolomics analysis. Trials could be investigator-initiated trials, or trials in which the drug company provides a portion but not all of the funding required. Both single investigator and multi-investigator grants should be considered that are designed to test a new agent, understand its mechanism of action, develop markers of sensitivity or resistance, with priority given for trials using new targeted combination therapy.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	FEBRUARY 8, 2016

CPRIT Financial Overview for FY 2016, Quarter 1

FY 2016, Quarter 1 Operating Budget

For the first quarter of FY 2016, CPRIT has expended or encumbered approximately $11.2 million, or 64%, of the agency's $17.6 million administrative budget between the Indirect Administration and Grant Review and Award Operations strategies. This administrative budget includes $200,000 in projected expenses for the 2015 conference. Otherwise, the primary items of expenditure remain staff salaries and service contracts, particularly the contract with SRA International for pre- and post-award grant management support services.

During this quarter, CPRIT received $15,076 in revenue sharing payments which was deposited into the General Revenue Fund (0001). Total revenue sharing payments received since CPRIT inception is slightly above $2.2 million. Through the end of November 2015, CPRIT had collected $171,020 in revenue from conference registration fees and $25,000 in product development application fees.

FY 2016, Quarter 1 Performance Measures

In October 2016, CPRIT reported performance to the LBB on the two output measures that have quarterly reporting requirements:

1) Number of People Served by Institute Funded Prevention and Control Activities and
2) Number of Entities Relocating to Texas for Cancer Research Related Projects.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $55.4 million in commercial paper notes on CPRIT's behalf in September 2015 to provide funds for CPRIT's FY 2016 operating costs and for grant award payments. TPFA refinanced the outstanding $300 million in General Obligation Commercial Paper Notes on October 29, 2015, at a long-term interest cost of 3.299867% and also issued in that same transaction $69.8 million for anticipated grant award expenses. These funds were disbursed to CPRIT at the agency's request in January 2016.

Cancer Prevention and Research Institute of Texas
LBB Quarterly Financial Report
As of November 30, 2015

Indirect Administration (B.1.1.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,413,921	$ 1,064,491		$ 305,709	758,782	29%	$ 407,612	$ 656,879
1002	Other Personnel Costs	51,000	51,000		4,018	46,982	8%	5,357	45,643
2001	Professional Fees and Services	1,015,500	962,000		351,544	610,456	37%	468,725	493,275
2003	Consumable Supplies	26,651	26,651		3,351	23,300	13%	4,467	22,184
2004	Utilities	64,921	64,921		1,219	63,702	2%	1,625	63,296
2005	Travel	36,095	36,095		14,657	21,438	41%	19,543	16,552
2006	Rent-Building	-	-		-	-	0%	-	-
2007	Rent-Machine and Other	24,995	24,995		1,062	23,933	4%	1,416	23,579
2009	Other Operating Expenses	349,402	822,980		100,842	722,138	12%	134,456	688,524
	Subtotal - Indirect Administration (B.1.1.)	**$ 2,982,485**	**$ 3,053,133**	**1.03%**	**$ 782,401**	**$ 2,270,732**	**26%**	**$ 1,043,201**	**$ 2,009,932**

Grant Review and Award Operations (A.1.3.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,679,624	2,686,966		$ 661,345	$ 2,025,621	25%	$ 881,794	$ 1,805,172
1002	Other Personnel Costs	3,726	3,726		13,967	(10,241)	0%	18,623	(14,897)
2001	Professional Fees and Services	11,040,000	11,630,462		9,705,799	1,924,663	83%	12,941,065	(1,310,603)
2003	Consumable Supplies	-	-		-	-	0%	-	-
2005	Travel	42,516	42,516		18,563	23,953	44%	24,750	17,766
2006	Rent - Building	33,534	33,534		8,176	25,358	24%	10,901	22,633
2007	Rent-Machine and Other	7,763	7,763		332	7,431	4%	443	7,320
2009	Other Operating Expenses	-	3,500		292	-	0%	389	-
	Subtotal - Grant Operations (A.1.3.)	**$ 13,807,163**	**$ 14,408,467**	**4.85%**	**$ 10,408,474**	**$ 3,996,784**	**72%**	**$ 13,877,966**	**$ 527,390**

Grants

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,340,035	$ 28,340,035		$ 13,247,742	$ 15,092,293	47%	$ 13,247,742	$ 15,092,293
4000	Grants - Research (A.1.1.)	251,955,763	$ 251,333,811		98,761,270	$ 152,572,541	39%	98,761,270	152,572,541
	Subtotal - Grants	**$ 280,295,798**	**$ 279,673,846**	**94.12%**	**$ 112,009,012**	**$ 167,664,834**	**40%**	**$ 112,009,012**	**$ 167,664,834**
	Grand Totals	**$ 297,085,446**	**$ 297,135,446**	**100.00%**	**$ 123,199,887**	**$ 173,932,350**	**41%**	**$ 126,930,179**	**$ 170,202,156**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of November 30, 2015

	11/01/2015 thru 11/30/2015	AY 16 Year to Date as of 11/30/2015
Beginning Balance : 11/1/2015		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 11/30/2015		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of November 30, 2015

	11/01/2015 thru 11/30/2015	AY 16 Year to Date as of 11/30/2015
Beginning Balance : 11/1/2015		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 685.64	$ 2,874.57
Total Increases	**$ 685.64**	**$ 2,874.57**
Reductions:		
Expenditures - Appropriated	$ 0.00	$ 0.00
	-	-
	-	-
Total Reductions	**$ 0.00**	**$ 0.00**
Ending Balance, 11/30/2015		**$ 2,874.57**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of November 30, 2015

		11/01/2015 thru 11/30/2015	AY 16 Year to Date as of 11/30/2015
Beginning Balance : 11/1/2015			**$ 62,102.00**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 25,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ 35,990.00	$ 171,020.00
(4)	Conference Registration Fees-Credit Card	$ 707.87	$ 4,036.42
Total Increases		**$ 36,697.87**	**$ 200,056.42**
Reductions:			
	Expenditures - Appropriated		$ -
	Credit Card Fees Expended	$ (729.29)	$ (4,036.42)
		$ -	$ -
Total Reductions		**$ (729.29)**	**$ (4,036.42)**
Ending Balance, 11/30/2015			**$ 258,122.00**

Cancer Prevention and Research Institute of Texas

General Revenue Fund Account - 0001

As of November 30, 2015

		11/01/2015 thru 11/30/2015	AY 16 Year to Date as of 11/30/2015
Beginning Balance : 11/1/2015			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ 4,959.25	$ 15,076.62
Total Increases		**$ 4,959.25**	**$ 15,076.62**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
	Sweep Account	$ (4,959.25)	$ (15,076.62)
		$ -	$ -
Total Reductions		**$ (4,959.25)**	**$ (15,076.62)**
Ending Balance, 11/30/2015			**$ -**

Note:

Cancer Prevention and Research Institute of Texas
FY 2016, Quarter 1 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	114,072				114,072	14.26%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00				0.00	0.00%
Percentage of Texas Regions with Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A		0.00%
Annual Age-adjusted Cancer Mortality Rate	155.3	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 50,775,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,575,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
				$ 125,200,000				
TOTAL ISSUED TO DATE				**$ 918,575,000**				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 50,775,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,575,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Will be disbursed to CPRIT December 2015	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
				$ 125,200,000				
TOTAL ISSUED TO DATE				**$ 918,575,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	APPROVAL OF FY 2016 INTERNAL AUDIT SERVICE CONTRACT
DATE:	FEBRUARY 8, 2016

Recommendation

Staff recommends that the Oversight Committee approve a contract for internal audit services with Weaver and Tidwell for FY 2016. The contract would be for a not to exceed amount of $232,500 for FY 2016 with three one-year renewal options through the end of FY 2019.

CPRIT staff determined that Weaver and Tidwell would provide the best value to the state based on the firm's experience as an internal auditor for other state agencies, the audit team's working knowledge of applicable state law and other requirements against which agency operations are measured, the depth and breadth of the audit team's expertise, and a competitive price for their services.

Background

CPRIT must contract with a certified public accounting firm to serve as the agency's outsourced internal auditor and perform audits on information security, commodity and service contracts, revenue, and cash management and perform follow-up procedures on pre-award and post award grant management grant contracting and information technology services outlined in the FY 2016 Internal Audit Plan submitted to the State Auditor's Office during fall 2015. CPRIT received six proposals in response to the Request for Proposal posted to the Electronic State Business Daily and CPRIT's website from November 30, 2015, through December 29, 2015.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	CHIEF COMPLIANCE OFFICER REPORT
DATE:	FEBRUARY 8, 2016

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies (T.A.C. § 701.7). In addition, the compliance officer must inquire into and monitor the timely submission status of required grant recipient reports and notify the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT grant compliance specialists monitor the status of grantee reports that are currently due. A summary of delinquent reports is produced by CPRIT's grant management system (CGMS) every week; this is the primary source used by CPRIT's compliance staff to follow up with grantees.

As of the end of January (CGMS report date January 29, 2016), 13 required grantee reports from 9 entities were not filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to expeditiously resolve filing issues.

Per the Oversight Committee's request at the November 2015 meeting, the agency was asked to examine grantee reporting requirements. A required reports matrix was developed to show the report name, filer, due date, and applicable statutory and administrative rule references. The frequency and volume of CPRIT's reports are largely the result of statutory requirements and audit findings, none of which have recommended less reporting or back-up documentation. While CPRIT may require more reports than federal institutions, it does so in order to verify that dollars are spent in accordance with CPRIT's statute and to maintain public trust in CPRIT's

operations. This information was formally presented to the Board Governance Subcommittee at its Thursday, February 4, 2016 meeting.

FSR Reviews

CPRIT's grant compliance specialists have performed 401 prepayment reviews of grantee Financial Status Reports (FSRs) during this quarter, bringing the fiscal year total to over 1,000 prepayment reviews. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for a second level review.

Annual Attestation (Self-Certification)

Grantees are required to submit an annual self-certification demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows grant compliance specialists to proactively work with the grantee towards full compliance prior to a desk review or on-site review. Grant compliance specialists are currently working with 12 grantees to remediate areas of non-compliance.

Desk Reviews

Fifty-five desk reviews have been performed so far this quarter, bringing the fiscal year total to 139 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission. Grant compliance specialists are actively working with six grantees to remediate desk review findings.

On-site Reviews

CPRIT compliance staff has performed three on-site reviews during the second quarter of FY2016; a total of 10 on-site reviews have been performed so far this fiscal year. On-site reviews may include examination of the grantee's financial and administrative operations, procurement and contracting policies and procedures, personnel policies and practices, payroll and timesheet policies, travel policies and records, and single audit compliance. No significant findings were identified during the on-site reviews.

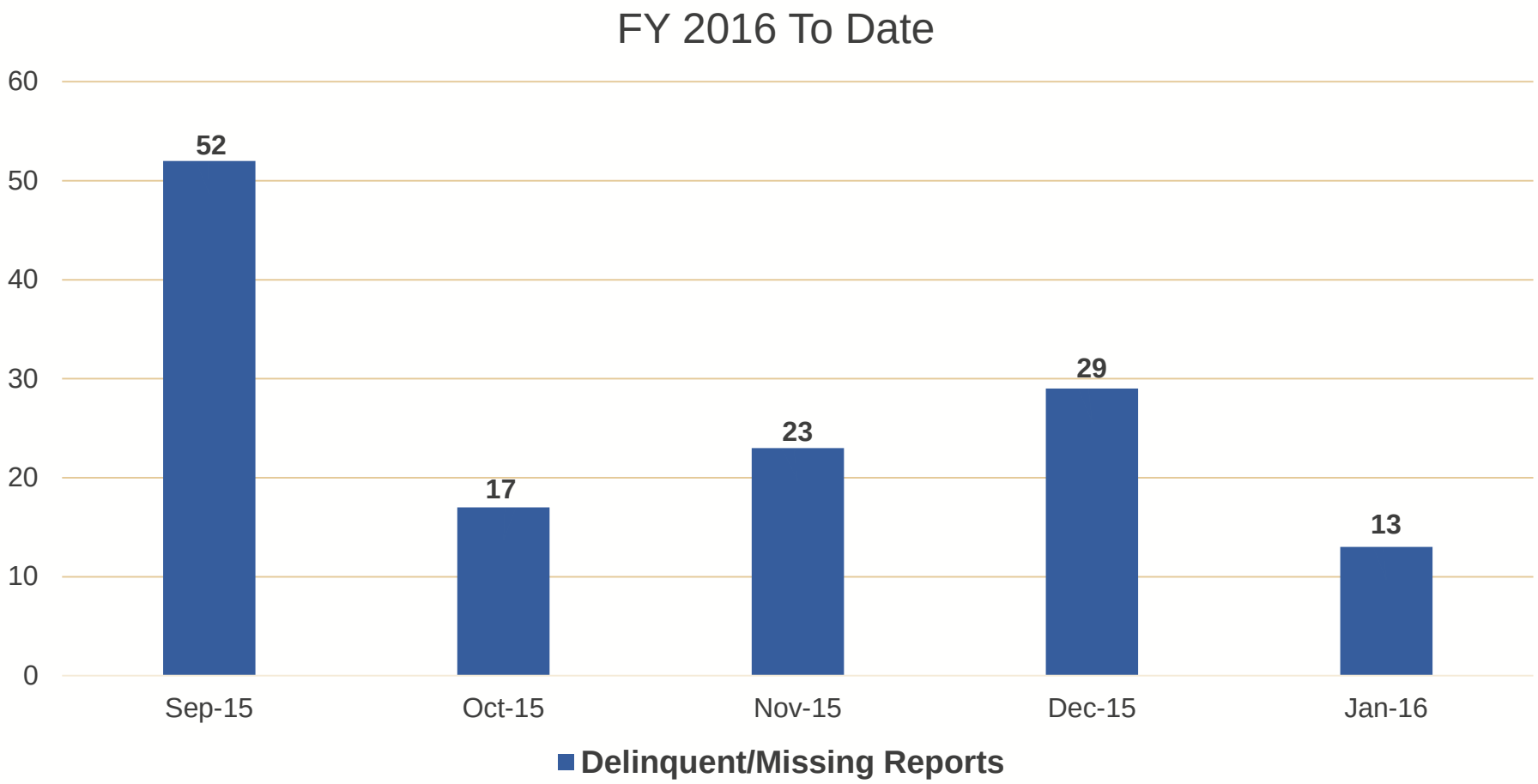
Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in CPRIT grant funds in the grantee's fiscal year must submit a single audit or have an audit performed according to an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the recipient's fiscal year end. Grant compliance specialists are currently working with eight grantees towards resolution of outstanding audit findings.

Training and Technical Assistance

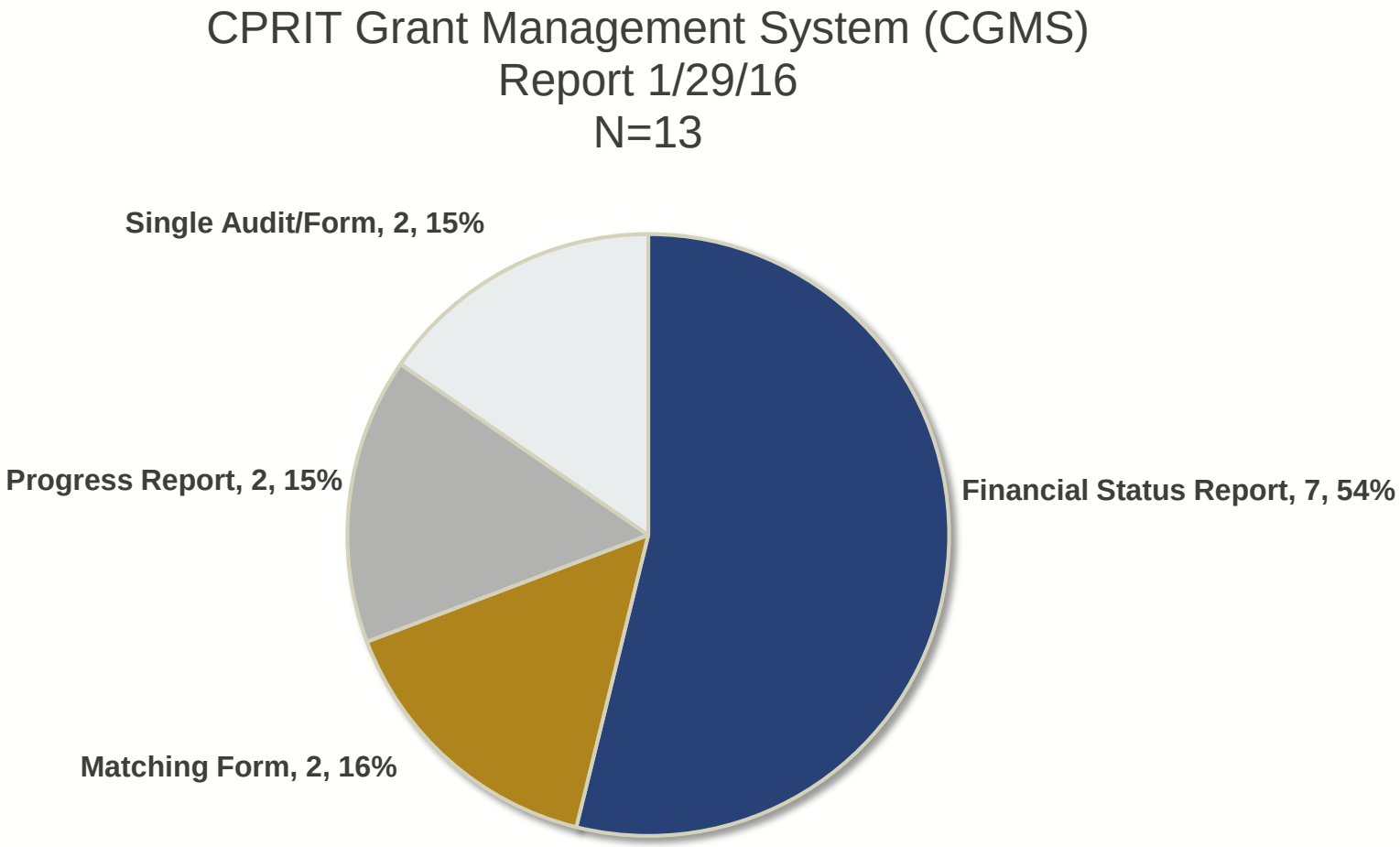
Grantee training webinars have been scheduled for March 30, 2016 and June 15, 2016. CPRIT staff will also travel to the Dallas area on April 25, 2016 to present at the National Council of University Research Administrators (NCURA) Region V meeting. These training opportunities will cover such topics as an overview of the compliance program and monitoring efforts, grantee reporting requirements, administrative rule changes, and helpful hints in navigating CPRIT's grants processes.

Grant Recipient Report Monitoring

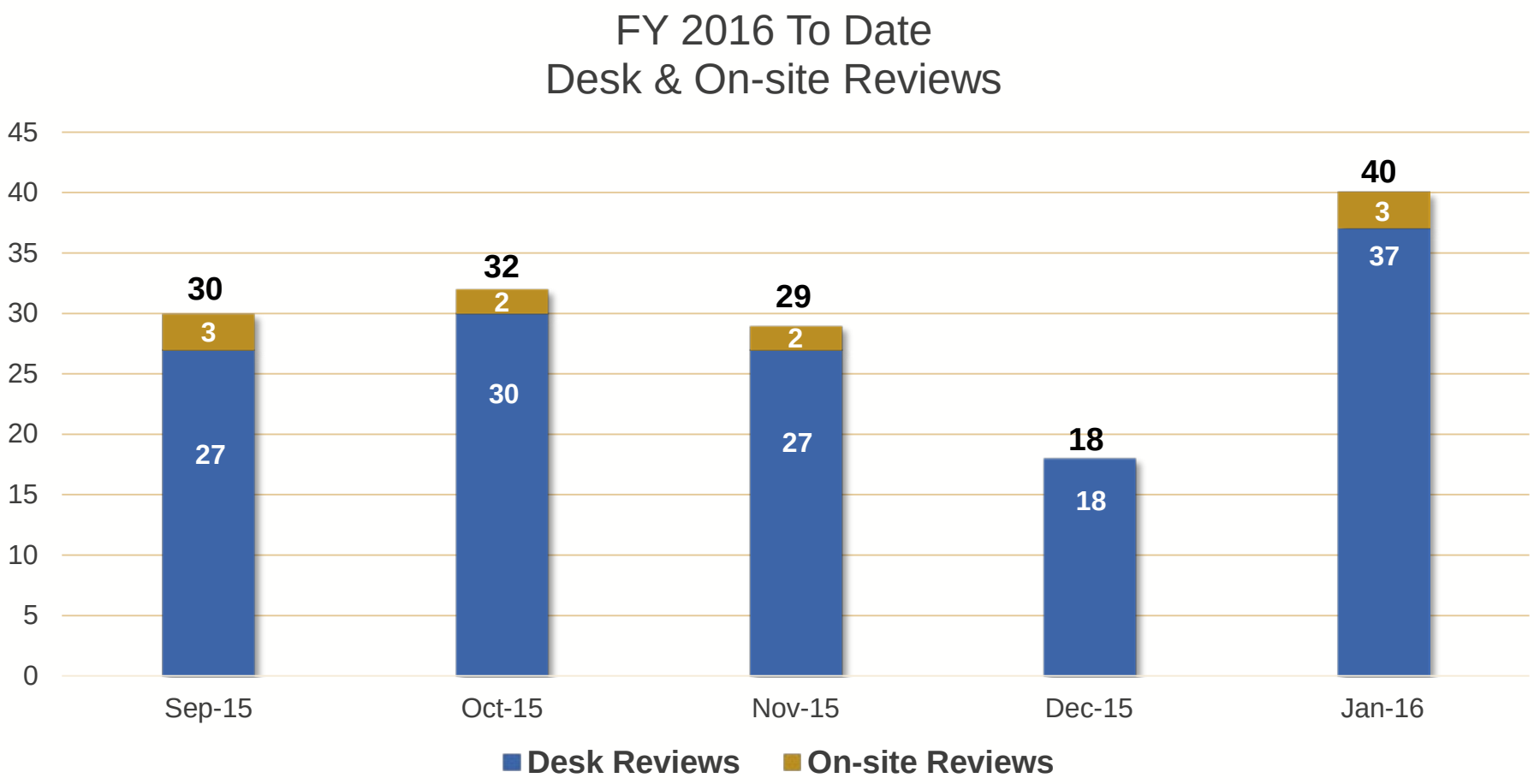


Reports Submitted: Approximately 6800/Annually. Average 570/Month.

Delinquent Reports by Type



Grantee Monitoring



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	BOARD GOVERNANCE SUBCOMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	CPRIT GRANTEE REPORTS ANALYSIS
DATE:	JANUARY 27, 2016

Summary

A Cancer Prevention and Research Institute of Texas (CPRIT) grantee is required to submit reports reflecting fiscal and programmatic progress throughout the course of the grant. Reporting frequency and document volume are primarily attributable to statutory, legislative, and audit requirements applicable to CPRIT and reflected in the agency's administrative rules. A table of reports to be submitted by a CPRIT grantee over the course of a project year and the basis for each report is attached to this memo for reference.

Required Reports

Required reports for CPRIT fall into three main categories: 1) Grant Expenditure Reports; 2) Progress Reports; and 3) Other Annual Reports. CPRIT's required reports are addressed in 25 Texas Administrative Code §§ 701 and 703, Texas Health & Safety Code § 102, and the Uniform Grant Management Standards (UGMS).

Grant Expenditure Reports

CPRIT grantees are required to have financial systems in place to monitor their grant expenditures. CPRIT grantees report expenditures via the submission of Financial Status Reports (FSRs) that include supporting documentation detailing how project costs from the previous quarter were incurred.

- Reimbursement of Grant Funds

CPRIT operates mainly on a reimbursement basis. Academic research and prevention grantees receive money from CPRIT after the grantees have expended their own funds consistent with a previously-approved annual budget for their CPRIT projects. Grant funds are disbursed to Product Development grantees in advance of incurring the expense; the money is advanced in tranches tied to the successful completion of certain project activities (e.g., completion of a Phase I clinical trial). Regardless of whether grants funds are reimbursed or advanced, all grantees must report the information to CPRIT via quarterly FSRs. A CPRIT grant accountant

completes an initial review of the FSRs and supporting documentation before routing them to a compliance specialist for final review and disposition.

- Frequency of Reports

The attention to financial and progress reporting is reflected in the statutory changes enacted in 2013 following the State Auditor's report. The findings and recommendations did not specifically address the frequency of required reports, but CPRIT's statute requires the agency to monitor grantee compliance with legal and contractual requirements and to report the information to the Oversight Committee on a quarterly basis. Receiving grant expenditure reports less frequently would make this monitoring obligation more difficult to fulfill.

- Back-up documentation

CPRIT grantees must submit supporting documentation (e.g., invoices, receipts, payroll, travel documents) that corroborates the expenditures listed on the FSR. Product development grantees are required to provide backup documentation for all expenses, while academic research and prevention grantees submit backup for expenses exceeding a certain amount, usually $750, unless additional information is necessary to determine whether the expense is eligible for reimbursement. The amount of documentation required by CPRIT and the level of scrutiny given to submitted documents and timeliness of those filings has increased. CPRIT's enhanced requirements are the result of the agency's implementation of audit recommendations made by the state auditor and its internal auditor. For example, the State Auditor found that:

> …for 85 (84.1 percent) of the 101 reimbursements, or approximately $9.4 million in reimbursements, CPRIT did not obtain detail to support that reimbursed expenditures such as payroll expenses, travel expenses, purchases, and service expenses were reasonable, necessary, and allowable. For those 85 reimbursements, grantees typically provided CPRIT with spreadsheets that summarized the expenditures they reported were related to the CPRIT grant for the applicable reporting period. However, CPRIT cannot ensure the accuracy and appropriateness of grantees' reported expenditures without obtaining detailed information and adequate documentation to support the expenditures reported on the spreadsheets.[1]

Similarly, CPRIT's internal auditor recommended:

> …grantees should be required to provide supporting invoices and receipts for all expenses incurred, including transactions that are internal to a grantee's entity, and submitted on the Financial Status Report regardless of dollar amount. We also

[1] Keel, John, An Audit Report on Grant Management at the Cancer Prevention and Research Institute of Texas and Select Grantees, 24 (January 2013).

recommend that a detailed description be provided by the grantee to show how the expenditure is appropriate to the award.

CPRIT's separate independent financial auditor also found a lack of documentation post-award and recommended the implementation of stronger review:

> Out of 47 of the 50 samples we tested, grantees did not provide in our judgment enough supporting documents with their financial status reports that would enable CPRIT to verify allowability, reasonableness and use of funds per the terms of their grant agreements…We recommend that CPRIT expedite its implementation of the adopted administrative rule for 50% matching fund requirements and strengthen its review of grant reimbursement requests to ensure only allowable costs are paid to grantees per the terms of the agreement.

Progress Reports

CPRIT requires grantees to submit annual progress reports, and may require additional reports throughout the year. A CPRIT progress report is evaluated by subject matter experts and must be approved before the grantee may receive funding for the next project year. The Program Officer may find that based on the annual report the grantee has not made sufficient progress to continue funding and the grant should be terminated.

Examples of other progress reports that may be required by CPRIT in addition to the annual report:

- CPRIT prevention grantees submit quarterly progress reports. Data reported by prevention grantees is used to report on CPRIT's performance measures set by Legislative Budget Board as required by the General Appropriations Act.

- Product development grantees submit a tranche report when the project goals and aims associated with the funding tranche are completed. (When the project goals and aims are completed at the time that the annual report is due, then a separate tranche report is not required.) The tranche report must be approved in order for the grantee to receive the next funding tranche.

Other Annual Reports

CPRIT grantees submit various reports during the course of the project year. All CPRIT grantees must submit the following reports annually in addition to the grant expenditure reports and annual reports:

- Historically Underutilized Businesses report (HUB)
- Annual Inventory Report (AIR)
- Revenue Sharing Form

- Single Audit Determination (SAD)

- Audit (if the grantee has expended at least $500,000 in state grant funds during a state fiscal year)

With the exception of the audit, most of the reports or forms are one-page reports available through CPRIT's electronic Grant Management System (CGMS) where the grantee must click a box on each form and provide relevant information, if applicable. If a grantee has used a HUB vendor, then the grantee provides the name of the vendor and amount. The AIR lists information on any equipment costing $5,000 or more that is purchased with grant funds. The revenue sharing form requires more information if product revenues have been received. Similar to the revenue sharing form, the SAD form requires a grantee to click a box to report whether an audit is required of the grantee. If required, the grantee must submit an annual single independent audit, a program specific audit, or an agreed upon procedures engagement based on the grantee's fiscal year within 30 days of the audit completion, but no later than nine months of the end of the grantee's fiscal year.

Academic research and product development grantees must also submit Matching Fund certification and verification forms annually. Based on information provided by the grantee and pulled from the project budget, the form calculates the dollar amount that the grantee must "match" (i.e. pay project costs with its own funds) for the budget year. The grantee also uses the form to verify that it expended its own funds as required for the previous year. Any matching fund discrepancy is calculated by CGMS and will be carried forward into the next year (in the event that the grantee paid more of its own funds into the project than required by law) or noted as a deficiency. CPRIT takes further action depending upon the size of the deficiency, which can include contract termination. Grantees must then provide documentation for the match.

CPRIT grantees may also submit change requests throughout the course of a project year. Requests by CPRIT grantees include re-budgeting, carry forwards, and a no-cost extension at the end of a grant period.

Conclusion

The frequency and volume of CPRIT's reports are largely the result of statutory requirements and audit findings, none of which have recommended less reporting or back-up documentation. During the past year, CPRIT has expanded its fiscal and compliance operations in order to better guide grantees through the reporting process. While CPRIT may require more reports than federal institutions, it does so in order to verify that state dollars are spent in accordance with CPRIT's statute and to maintain public trust in CPRIT's operations.

Required Reports Matrix

January 2016

Report	Filer	Due Date	Health & Safety Code Reference	Texas Administrative Code Reference	Uniform Grant Management Standards Reference
Quarterly Financial Status Report	All grant recipients	90 days after the end of the state fiscal quarter	H&SC 102.0535(a)(2)	T.A.C. § 703.21(b)(1)	UGMS III Subpart C 41(b)(2)(3)
Final Financial Status Report	All grant recipients	90 days after the end of state fiscal quarter	H&SC 102.0535(a)(2)	T.A.C. § 703.14(d)	UGMS III Subpart C 41(b)(2)(3)
Quarterly Progress Report	Prevention grant recipients	15 days after the end of the state fiscal quarter	H&SC 102.0535(a)(3)		UGMS III Subpart C 40(b)(1)
Annual Progress Report	All grant recipients	60 days after the anniversary of the grant contract effective date	H&SC 102.0535(a)(3)	T.A.C. § 703.21(b)(3)(B)	UGMS III Subpart C 40(b)(1)
Tranche Report	Commercialization/ Product Development grant recipients	Upon completion of milestones for specific tranche	H&SC 102.0535(a)(3)	T.A.C. § 703.21(b)(3)(G)	
Final Progress Report	All grant recipients	Within 90 days of grant contract termination date	H&SC 102.0535(a)(3)	T.A.C. § 703.21(b)(3)(C)	UGMS III Subpart C 40(b)(1)
Matching Funds Certification/ Verification Form	Research grant recipients (including Commercialization/ Product Development)	Contract execution (certification)	H&SC 102.255(c)(2), (d)	T.A.C. § 703.21(b)(3)(B)(x)	UGMS III Subpart C 24(b)(6)
Inventory Report	All grant recipients	60 days after the anniversary of the grant contract effective date		T.A.C. § 703.21(b)(3)(B)(iv)	UGMS III Subpart C 32(d)(1)(2)(3)

Report	Filer	Due Date	Health & Safety Code Reference	Texas Administrative Code Reference	Uniform Grant Management Standards Reference
Revenue Sharing Form	All grant recipients	60 days after the anniversary of the grant contract effective date	H&SC § 102.256	T.A.C. § 703.21(b)(3)(B)(xi)	UGMS III Subpart C 25(b)(h)
HUB/Buy Texas Form	All grant recipients	60 days after the anniversary of the grant contract effective date	H&SC §§ 102.258 & 102.259	T.A.C. § 703.21(b)(3)(B)(vi)	UGMS III Subpart C 36(e)(1)
Single Audit Determination Form	All grant recipients	60 days after the anniversary of the grant contract effective date		T.A.C. § 703.21(b)(3)(B)(xii)	UGMS III Subpart C 26(d)
Audit	Recipients that expend $500,000 or more in state awards in the recipient's fiscal year	Within 30 days of receipt, but no more than 270 days after the recipient's fiscal year end		T.A.C. § 703.13(b)(3)	UGMS IV § 200(a)(b) UGMS IV § 320(a)
Close Out Documents	All grant recipients	Within 180 days of grant contract termination date		T.A.C. § 703.14(d)	UGMS II Subpart D 50(a) UGMS III Subpart D 50(b)

Health & Safety Code general cites for reporting standards:
102.051(a)(3), 102.051(a)(5), 102.0535, 102.255(d), 102.260

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**NED HOLMES, CHAIR, BOARD GOVERNANCE SUBCOMMITTEE**
Subject:	**INTENTION TO RECOMMEND APPROVAL AND PUBLICATION OF PROPOSED ADMINISTRATIVE RULE CHANGES**
Date:	**FEBRUARY 10, 2016**

Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee vote to approve proposed changes to 25 T.A.C. Chapters 702 and 703 for publication in the *Texas Register*. The Board Governance Subcommittee reviewed and discussed the proposed amendments with CPRIT's General Counsel at its meeting on February 4, 2016.

Discussion

The proposed rule changes affect professional conflicts of interest, the limitation on the use of grantee funds, and financial status report (FSR) reimbursement waivers. The proposed order summarizes the changes. The Board Governance Subcommittee reviewed the proposed amendments and recommends that the Oversight Committee approve publication in the *Texas Register*. CPRIT will solicit comments on the proposed change from the public. All comments will be summarized and considered by the Oversight Committee before adopting the rule changes at the May Oversight Committee meeting.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**SUMMARY OF PROPOSED RULE CHANGES TO BE PROPOSED FEBRUARY 2016**
Date:	**FEBRUARY 9, 2016**

Summary

There are three proposed administrative rule changes for the Oversight Committee's consideration on February 17, 2016. The three changes provide clarity regarding professional conflicts of interest and authorized expenses, and establish a process for a grantee to appeal the waiver of expense reimbursement. After approval, CPRIT will publish the proposed changes in the *Texas Register* for public comment.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes. State law requires agencies to set policy using a rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the final policy is adopted. CPRIT staff proposes the following three changes to the agency's administrative rules for the Oversight Committee's consideration:

- Rule § 702.11 "Conflicts of Interest Requiring Recusal" - The proposed amendment clarifies that serving as a consultant or contractor for a grant applicant constitutes a professional conflict of interest. This additional description fills a gap that currently exists.

- Rule § 703.12(b)(1) "Limitation on Use of Funds" – The change adds visa fees to the expenses that are not authorized to be reimbursed by CPRIT grant funds.

- Rule § 703.21(b)(2) – The amendment adds an appeal process if a grantee's reimbursement of project expenses is waived by CPRIT. A grantee waives reimbursement for otherwise allowable expenses incurred in a fiscal quarter if the grantee fails to submit a financial status report within 120 days after the end of the fiscal quarter. The proposed process allows the grantee to appeal the waiver of reimbursement. The

grantee's appeal must be in writing and submitted to the CEO through CPRIT's electronic grant management system. The CEO's decision to approve the appeal and reverse the waiver or to deny it is final. However, after discussion with the Board Governance subcommittee, the proposed rule reflects the grantee's option to seek reconsideration from the Oversight Committee if the CEO denies the grantee's appeal. The grantee must submit a written request to the CEO within 10 days of the CEO notifying the grant recipient of the decision regarding the appeal. If at least three Oversight Committee members agree, the Oversight Committee will consider the grantee's appeal at an open meeting. The Oversight Committee's decision is final.

Next Steps

Once approved by the Oversight Committee, CPRIT will publish the proposed rules in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT staff will post the proposed rules on CPRIT's website and announce the opportunity for public comment via the CPRIT electronic list serve. CPRIT legal staff will summarize all public comments for the Oversight Committee's consideration when approving the final rule changes in May.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Summary of Proposed Rule Changes
To Be Published February 2016

Rule § 702.11 Conflicts of Interest Requiring Recusal

The recommended change clarifies that **it is a professional conflict of interest to serve as a consultant or contractor for a grant applicant**. A peer review member, CPRIT employee, or Oversight Committee member with a professional conflict of interest must recuse himself or herself from deliberations on the grant applicant. The proposed change also expands the scope of the professional conflict of interest to include the time that the individual is actively seeking to represent the grant applicant.

Rule § 703.12 Limitation on Use of Funds

The proposed amendment **adds visa fees to the expenses that are not authorized to be reimbursed** by CPRIT grant funds.

Rule § 703.21 Monitoring Grant Award Performance and Expenditures

The recommended change provides **a process for grantees to appeal the waiver of reimbursable costs**. Under CPRIT's current rules, a grantee waives reimbursement of otherwise allowable costs if the grantee does not submit the required financial status report (FSR) within 120 days of the end of the fiscal quarter. Waiver has been an important tool to ensure that grantees remain compliant; however, there may be circumstances beyond the control of the grantee that justify allowing reimbursement for otherwise waived costs. The rule change provides a process for the grantee to seek reconsideration of the waiver. The CEO is responsible for considering and approving the appeal of the waiver. The CEO's decision is final unless the grantee seeks reconsideration of the CEO's decision within 10 days. If at least three members of the Oversight Committee agree to hear the request for reconsideration, the Oversight Committee will consider the grantee's appeal at an open meeting. The Oversight Committee's decision is final.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | www.cprit.state.tx.us

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 702. Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute

The Cancer Prevention and Research Institute of Texas (Institute) proposes an amendment to § 702.11 regarding what constitutes a professional conflict of interest. Specifically, the amendment clarifies that an individual subject to the rule has a professional conflict of interest if the individual performs work as a consultant or a contractor for a grant applicant. The amendment also expands the scope of the rule to include the time that an individual subject to the rule actively seeks to represent an entity receiving or applying to receive Institute funds.

Background and Justification

The proposed change to § 702.11(d)(4) addresses one type of professional conflict of interest an individual subject to the rule may hold. Currently, an individual subject to the rule has a professional conflict of interest if he or she is representing "in business or law" an entity receiving or applying to receive money from the Institute. The proposed amendment clarifies that such representation includes serving as a consultant or contractor to the grant applicant. It also expands the applicability of the rule to include the time that the individual is actively seeking to represent a grant applicant. Finally, the proposed amendment provides examples of activities that constitute "actively seeking to represent" such that the rule is invoked.

Fiscal Note

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect there will be no foreseeable implications relating to costs or revenues for state or local government as a result of enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated as a result of enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties.

Small Business and Micro-business Impact Analysis

Ms. Doyle has determined that the rule changes shall not have an effect on small businesses or on micro businesses.

Written comments on the proposed rule changes may be submitted to Ms. Doyle, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711 no later than March 7, 2016. Parties filing comments are asked to indicate whether or not they support the

rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The rule change is proposed under the authority of the Texas Health and Safety Code Annotated, §§ 102.106 and 102.108, which allow the Oversight Committee to adopt additional; conflict of interest standards and provides the Institute with broad rule-making authority to administer the chapter, respectively. Ms. Doyle has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article or code that is affected by these rules.

RULE §702.11 Conflicts of Interest Requiring Recusal

(a) For purposes of this chapter, a Conflict of Interest exists when an individual subject to this rule has an interest in the outcome of a Grant Application submitted by an entity receiving or applying to receive money from the Institute such that the individual is in a position to gain financially, professionally, or personally from either a positive or negative evaluation of the Grant Application. Individuals subject to this rule are:

(1) Oversight Committee Members;

(2) Institute employees;

(3) Scientific Research and Prevention Programs Committee Members;

(4) Program Integration Committee Members; and

(5) Independent Contractors that perform services associated with the Grant Review Process on behalf of the Institute, such as facilitating grant review activities, evaluating the intellectual property held by or licensed to a Grant Applicant, or performing a business management due diligence review.

(b) Except under exceptional circumstances as provided in §702.17 of this chapter (relating to Exceptional Circumstances Requiring Participation), an individual who has a financial, professional, or personal interest, as set forth herein, in an entity receiving or applying to receive money from the Institute shall recuse himself or herself and may not participate in the review, discussion, deliberation, or vote related to the entity.

(c) A financial Conflict of Interest exists if the individual subject to this rule or a Relative of the individual subject to this rule:

(1) Owns or controls, directly or indirectly, an ownership interest in an entity receiving or applying to receive money from the Institute or in a foundation or similar organization affiliated with the entity~~.~~;

(A) Interests subject to this provision include sharing in profits, proceeds, or capital gains. Examples of ownership or control, include but are not limited to owning shares, stock, or otherwise, and are not dependent on whether voting rights are included~~.~~;

(B) It is not a financial Conflict of Interest if the ownership interest is limited to shares owned via an investment in a publicly traded mutual fund or similar investment vehicle so long as the individual subject to this rule does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle~~.~~;

(2) Could reasonably foresee that an action taken by the Scientific Research and Prevention Programs Committee, the Program Integration Committee, the Institute, or its Oversight Committee related to an entity receiving or applying to receive money from the Institute could result in a financial benefit to the individual~~.~~; or

(3) Has received a financial benefit from the Grant Applicant unrelated to the Grant Application of more than $5,000 within the past twelve months. This total includes fees, stock and other benefits. It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include diversified mutual funds or similar investment vehicle in which the person does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle.

(d) For purposes of this rule, a professional Conflict of Interest exists if the individual subject to this rule or a Relative of the individual subject to this rule:

(1) Is a member of the board of directors, other governing board or any committee of an entity or of a foundation or similar organization affiliated with an entity receiving or applying to receive money from the Institute during the same Grant Review Cycle;

(2) Serves as an elected or appointed officer of an entity receiving or applying to receive money from the Institute or of a foundation or similar organization affiliated with the entity;

(3) Is an employee of or is negotiating future employment with an entity receiving or applying to receive money from the Institute or a foundation or similar organization affiliated with the entity;

(4) Represents in business or law, including actively seeking to represent, an entity receiving or applying to receive money from the Institute or a foundation or similar organization affiliated with the entity;

(A) Representation that constitutes a professional Conflict of Interest includes providing services as a consultant or contractor;

(B) "Actively seeking to represent" includes activities such as responding to a request for proposals or qualifications issued by the entity applying to receive money from the Institute, providing a solicited or unsolicited proposal for work to the entity applying

to receive money from the Institute, and negotiating terms of service for representation even if a final agreement has not yet been executed;

(C) For the purposes of this rule, an individual is no longer considered to be actively seeking to represent an entity if that entity has selected another provider or has notified the individual that the individual's services are not needed;

(5) Is a colleague, scientific mentor, or student of a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application, or is conducting or has conducted research or other significant professional activities with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application within three years of the date of the review;

(6) Is a student, postdoctoral associate, or part of a laboratory research group for a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application or has been within the past six years;

(7) Is engaged or is actively planning to be engaged in collaboration with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application; or

(8) Has long-standing scientific differences or disagreements with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application that are known to the professional community and could be perceived as affecting objectivity.

(e) For purposes of this rule, a personal Conflict of Interest exists if a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application or an applicant is a Relative or close personal friend of an individual subject to this rule.

(f) Nothing herein shall prevent the Oversight Committee from adopting more stringent standards with regard to prohibited conflicts of interest.

(g) The General Counsel and Chief Compliance Officer may provide guidance to individuals subject to this section on what interests would constitute a Conflict of Interest or an appearance of a Conflict of Interest.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (Institute) proposes amendments to §§ 703.12 and 703.21 regarding authorized grant expenses and a process to appeal a waiver of reimbursement of project costs. The proposed changes affect financial reimbursement paid to grant recipients.

Background and Justification

The proposed change to § 703.12 clarifies that expenses associated with acquiring or maintaining a visa are not authorized expenses to be paid with grant funds. The proposed change to § 703.21 provides a process for a grant recipient to appeal to the Institute a waiver of reimbursement costs. Currently, there is no process in place for a grant recipient to appeal a waiver of costs caused when the grant recipient fails to receive a deferral or submit a required financial status report (FSR) within 30 days of the FSR due date. Pursuant to the proposed change, a grant recipient may provide a written appeal that demonstrates good cause for not submitting the FSR within the required timeframe. The Chief Executive Officer will review the appeal, and if approved, must notify the Oversight Committee.

Fiscal Note

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect there will be no foreseeable implications relating to costs or revenues for state or local government as a result of enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated as a result of enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties.

Small Business and Micro-business Impact Analysis

Ms. Doyle has determined that the rule changes shall not have an effect on small businesses or on micro businesses.

Written comments on the proposed rule changes may be submitted to Ms. Doyle, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than March 28, 2016. Parties filing comments are asked to indicate whether or not they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically

to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The rule changes are proposed under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle, the Institute's General Counsel, has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article or code that is affected by these rules.

RULE §703.12 Limitation on Use of Funds

(a) A Grant Recipient may use Grant Award funds only for Cancer Research and Cancer Prevention projects consistent with the purpose of the Act, and in accordance with the Grant Contract. Grant Award funds may not be used for purposes other than those purposes for which the grant was awarded. The Institute may require a Grant Recipient to repay Grant Award funds if the Grant Recipient fails to expend the Grant Award funds in accordance with the terms and conditions of the Grant Contract and the provisions of this chapter.

(b) Grant Award funds must be used for Authorized Expenses.

(1) Expenses that are not authorized and shall not be paid from Grant Award funds, include, but are not limited to:

(A) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(B) Contributions to a contingency reserve or any similar provision for unforeseen events.

(C) Contributions and donations made to any individual or organization.

(D) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(E) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(F) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(G) An honorary gift or a gratuitous payment.

(H) Interest and other financial costs related to borrowing and the cost of financing.

(I) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(J) Liability insurance coverage.

(K) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(L) Professional association fees or dues for the Grant Recipient or an individual.

(M) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(N) Patient support services costs relating to services such as personal care items and financial assistance for low-income clients.

(O) Fees for visa services.

(2) Additional guidance regarding Authorized Expenses for a specific program may be provided by the terms of the Grant Contract and by the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from UGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(3) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Authorized Expense.

(c) A Grant Recipient of Grant Award funds for a Cancer Research or Cancer Prevention project may not spend more than five percent (5%) of the Grant Award funds for Indirect Costs.

(d) The Institute may not award more than five percent (5%) of the total Grant Award funds for each fiscal year to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds that are to be expended by a Grant Recipient for facility purchase, construction, remodel, or renovations are subject to the following conditions:

(1) The use of Grant Award funds must be specifically approved by the Chief Executive Officer with notification to the Oversight Committee;

(2) Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit Cancer Prevention and Research;

(3) If Grant Award funds are used to build a capital improvement, then the state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award funds used to pay for the capital improvement. If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale.

(e) The Institute may not award more than ten percent (10%) of the money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute to be used for Cancer Prevention and Control programs during any year. Grant Awards for Cancer Prevention research projects shall not be counted toward the Grant Award amount limit for Cancer Prevention and Control Programs. For purposes of this subsection, the Institute is presumed to award the full amount of funds available.

RULE §703.21 Monitoring Grant Award Performance and Expenditures

(a) The Institute, under the direction of the Chief Executive Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review - Quarterly financial status reports shall be submitted to the Institute within 90 days of the end of the state fiscal quarter (based upon a September 1 - August 31 fiscal year). The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Financial Status Reports – Except as provided herein, ~~T~~the Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the financial status report (FSR) for that quarter is not submitted to the Institute within 30 days of the FSR due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.

(A) For purposes of this rule, the "FSR due date" is 90 days following the end of the state fiscal quarter.

(B) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original FSR due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the FSR.

(C) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.

(i) The appeal shall be in writing, provide good cause for failing to submit the FSR within 30 days of the FSR due date, and be submitted through CPRIT's Grant Management System.

(ii) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and provided through CPRIT's Grant Management System.

(iii) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.

(iv) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in subsection (iii).

(v) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.

(vi) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.

(vii) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.

(viii)Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to subsection (1) of this section.

(ix) This subsection applies to any waivers of its reimbursement decided by the Institute on or after September 1, 2015.

(3) Grant Progress Reports - The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) The annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form.

(C) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(D) The Grant Progress Report will be evaluated by a grant manager pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff.

(E) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).

(F) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(G) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Awards funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is filed.

(H) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(4) Desk Reviews - The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews - The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports - The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**NED HOLMES, CHAIR, BOARD GOVERNANCE SUBCOMMITTEE**
Subject:	**INTENTION TO RECOMMEND APPROVAL OF FINAL ORDER ADOPTING ADMINISTRATIVE RULES CHANGES**
Date:	**FEBRUARY 10, 2016**

Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee vote to approve a final order adopting changes to T.A.C. §§ 703.3, 703.11, 703.12, 703.14, 703.20, and 703.21.

Discussion

The Oversight Committee preliminarily approved several rule changes at its November 2015 meeting. The changes affect grant applications, matching funds, the prevention cap, no cost extension approval, tobacco-free policy waivers, grantee report due dates, and the report approval process. CPRIT received comments from two institutions regarding the proposed changes to §§ 703.13 and 703.21.

The Board Governance Subcommittee reviewed the comments and final order with CPRIT's General Counsel. The Board Governance Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule changes.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**SUMMARY OF PROPOSED RULE CHANGES TO BE ADOPTED FEBRUARY 2016**
Date:	**FEBRUARY 9, 2016**

Summary

The proposed administrative rule changes to Chapter 703, originally considered by the Oversight Committee in November 2015, are ready for final adoption. CPRIT received comments from two grantee institutions regarding the proposed changes after publication of the rule changes in the *Texas Register*. CPRIT legal staff recommends that the Oversight Committee adopt the rule changes with a few modifications suggested by the comments received. Once the Oversight Committee approves the final order, CPRIT will submit the rule changes to the Secretary of State and the changes will be considered final and effective 20 days later.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes. State law requires agencies to set policy using the rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy. The proposed rule changes preliminarily approved by the Oversight Committee in November affect various aspects of the processes related to grants for cancer prevention and research. Attached to this memo is a summary of the proposed changes.

CPRIT published the proposed rules in the December 4 and December 25 editions of the *Texas Register*, as well as solicited public comment via CPRIT's website. Texas Tech, a CPRIT grantee, submitted a comment requesting that CPRIT not remove a "program specific independent audit," as originally proposed, from the three options available for grantees to fulfill the audit requirement. CPRIT originally proposed to eliminate the option upon the advice of its internal auditor that the program specific independent audit is duplicative of the agreed upon procedures option. However, after discussion with Texas Tech, CPRIT staff recommends retaining the program specific independent audit option. This means that the rule will remain as it appears before the proposed change in November. Therefore, § 703.13 will not be published again or part of the final order.

M.D. Anderson, another CPRIT grantee, submitted comments addressing two issues. One issue was outside of the scope of the proposed rules. CPRIT legal staff advised M.D. Anderson how to submit a petition for adoption of rules to initiate a rulemaking process if it was inclined to pursue the non-germane change. M.D. Anderson also commented regarding § 703.21(b)(2)(C), seeking clarity on how a grantee will know if additional time for the grantee to submit financial status reports is approved. CPRIT legal staff recommends the clarifying language that has been added to the proposed amendment to make it clear that the Program Officer's approval of additional time must be in writing and stored in CPRIT's electronic grant management system. The additional language is a non-substantive change and will make record keeping of approvals clear.

The final order corrects a typographical error also affecting § 703.21(b)(2)(C). The subsection should read: "Notwithstanding subsection (2), in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding FSR(s). The Program Officer's approval may cover more than one FSR and more than one fiscal quarter." The word "one" was omitted from the last sentence of the subsection. The change does not substantially affect the meaning of the rule as it was originally proposed.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Summary of Proposed Rule Changes
To Be Adopted February 2016

Rule § 703.3 Grant Applications

The first change **removes the requirement that a Request for Applications (RFAs) be published in the Texas Register**. RFAs will still be published on CPRIT's website and announced via an electronic list serve messaging service. This amendment removes a duplicative step in the RFA process that is less effective than other methods used to publish RFAs.

The second change to § 703.3 adds a new subsection **explaining that CPRIT staff or CPRIT's third party grants administrator may contact the grant applicant to seek clarification** on information provided in the grant application or to request additional information to facilitate the administrative review process. This change addresses occasional issues that arise when information on a document submitted by a grant applicant is unclear or the document appears to be missing a page. Requests for clarification or additional information must be approved by the Program Officer before the grant applicant is contacted. A record of requests will be made for review by the Chief Compliance Officer.

Rule § 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

The proposed amendment to the matching requirement **changes the due date of matching verification forms**. Currently, these forms are due 60 days after the anniversary date of the effective date of the grant contract. Matching verification forms are based on grantee expenditures as reported in each Financial Status Report (FSRs) and cannot be completed until the last FSR of the last quarter of the fiscal year is submitted. FSRs are due 90 days after the end of the fiscal quarter, which occurs after the current due date of the matching verification form. This amendment changes the matching verification form due date so that it falls after the submission of the last quarter FSR.

Rule § 703.12 Limitation on Use of Funds

The proposed amendment clarifies that **the annual ten percent cap on the allocation of grant award funds to cancer prevention grants is calculated based upon the "full amount of grant award funds available to be awarded for the fiscal year" announced by CPRIT's CEO** at the first regular Oversight Committee meeting of the fiscal year (and updated periodically). The clarification is necessary because unanticipated declinations of research grant awards, particularly recruitment awards, after the last regular meeting of the fiscal year may impact the calculation of the total amount available to the prevention program. Specifying the expected amount of the total award funds available provides budgetary certainty for the prevention program and increases the transparency of CPRIT's processes.

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Rule § 703.14 Termination, Extension, and Close Out of Grant Contracts

The proposed amendment implements a **process for reviewing and approving no cost extensions that are requested after the specified due date**. By rule, no cost extensions are due no sooner than 180 days and no later than 30 days before the end date of the grant contract. The amendment allows the Chief Executive Officer (CEO) to review and approve a request submitted outside the specified time and approve it for good cause. If approved, the CEO must provide a written justification to the Oversight Committee.

Rule § 703.20 Certification of Tobacco-Free Policy for Grant Recipients

The proposed amendment specifies what a grantee must do in order to **request a waiver to the tobacco free policy for research purposes**. If a research project is conducted at the entity that requires tobacco, the grantee must specify the research project conducted with the use of tobacco as well as the location where the project is conducted.

Rule § 703.21 Monitoring Grant Award Performance and Expenditures

One of the proposed amendments would allow a grantee **more time in filing required grantee reports if the execution date of a grant contract occurs after the effective date**. Due date of grantee reports are based off of the effective date of a grant contract; however, in some cases a contract is not executed until after the effective date, thus giving a grantee less time to submit reports. The rule change permits the Program Officer to approve time to submit reports that are late because of a delay in starting the project after the effective date. A non-substantive change has been made to the proposed amendment to clarify that the Program Officer's approval will be in writing and available through CPRIT's grant management system.

This rule is also amended to **require the following reports be approved by CPRIT (as opposed to submitted) in order for a grantee to receive disbursement of grant funds: matching funds, progress reports (including annual, quarterly, and final), and FSRs**. This change was recommended by CPRIT's internal auditors.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to §§ 703.3, 703.11, 703.12, 703.14, 703.20, and 703.21 regarding Requests for Applications, clarification on grant applications, matching form due dates, the prevention percentage of overall grant funds, no cost extensions, tobacco free policy waivers, report due dates, and report approval rules. All of the proposed amendments, except for the amendment to § 703.12, were published in the December 4, 2015, issue of the Texas Register (40 TexReg 8722). The proposed amendment to § 703.12 was published in the December 25, 2015, issue of the *Texas Register* (40 TexReg 9459). After consideration of the public comments responsive to the rule change proposed for § 703.13, the Institute will not adopt a rule change to § 703.13.

Reasoned Justification

The proposed amendments affect various aspects of the processes related to grants for cancer prevention and research. One proposed amendment removes the requirement that requests for applications (RFAs) be published in the *Texas Register*, which eliminates a duplicative step when RFAs are announced on the CPRIT website and listserv. Another proposed amendment clarifies that CPRIT staff or CPRIT's third party grants administrator may contact the grant applicant to seek clarification on information provided in a grant application. The proposed amendments also change the due date of matching verification forms, clarify the annual ten percent cap on the allocation of grant award funds to cancer prevention grants, and directs the CEO to announce the full amount of grant award funds that are available to be awarded for the fiscal year. A proposed amendment to the "no cost extension" request process allows CPRIT's Chief Executive Officer to review and approve a request that is submitted outside of the specified deadline. Another proposed amendment allows grantees to request a waiver to the tobacco free policy; this is applicable to research projects that require tobacco and are conducted at the grantee's institution. The last series of proposed amendments affect grantee reports. One proposed amendment allows a grantee to receive more time in submitting required reports that are due before the execution date of a contract. Another proposed amendment requires matching fund reports, progress reports, and FSRs be approved by, rather than simply submitted to, the Institute in order for a grantee to receive disbursement of grant funds.

A typographical error to the proposed amendment § 703.21(b)(2)(C) must be corrected. The subsection should read: "Notwithstanding subsection (2), in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding FSR(s). The Program Officer's approval may cover more than one FSR and more than one fiscal quarter." The word "one" was omitted from the last sentence of the subsection. This correction does not substantially change the meaning of the subsection as it was originally proposed.

Summary of Public Comments and Staff Recommendation

CPRIT received public comments from Kimberly F. Turner, Chief Audit Executive, Texas Tech University (Texas Tech) regarding proposed changes to § 703.13 and from Wesley Harrott, Associate Vice President, Research Administration, The University of Texas M.D. Anderson Cancer Center (M.D. Anderson) regarding the proposed changes to § 703.21.

Texas Tech submitted a comments in reference to the proposed change to § 703.13, which eliminates a program specific independent audit from the options a grantee may use to fulfill the audit requirement. Texas Tech contends that the program specific independent audit should remain a choice for grantees. In its public comment, Texas Tech asserts that a program specific independent audit is different from an agreed upon procedures audit. It is Texas Tech's opinion that retaining the option for a program specific independent audit, "provides a higher level of assurance as to the proper expenditure of CPRIT funds." While the agency does not concede the qualitative comparison made between the program specific independent audit and the agreed upon procedures option, CPRIT is persuaded that the program specific independent audit should remain an option for grantees at this time. The change originally proposed by the CPRIT will not be made. Texas Tech also comments suggesting that CPRIT obtain an annual audit of all expenditures for all grants made to institutions of higher education as defined by Texas Education Code § 61.003. Texas Tech contends that, "This statewide engagement could be obtained at a much lower cost than the combined cost of multiple engagements the various higher education grant recipients must currently obtain." CPRIT declines to make this change to the rule because it is outside the scope of this proposed rulemaking.

M.D. Anderson submitted comments regarding proposed changes to § 703.21. M.D. Anderson makes a general request that the rule be changed "to add a reasonable timeline for the CPRIT approval process e.g. 30 days for all reports and documents so that the disbursement of funds will be received in a timely manner." CPRIT declines to make this change to the rule because it is outside of the scope of the proposed rulemaking.

M.D. Anderson also comments with regard to the proposed change to § 703.21(b)(2)(C), seeking clarity on how CPRIT will inform the grant recipient of the approval for additional time to prepare and submit additional FSRs. CPRIT has made a clarifying change to the proposed amendment to make clear that the Program Officer's approval will be in writing and maintained in CPRIT's grant management system. While it is likely that CPRIT staff and the grant recipient will be communicating contemporaneously about the pending approval for additional time to prepare and submit outstanding FSRs, this non-substantive change ensures that the grant recipient will be notified of the Program Officer's approval via CPRIT's grant management system.

The amendment originally proposed to § 703.13 and published in the December 4, 2015, edition of the *Texas Register* will not be made. The proposed amendments to § 703.21 will be republished to reflect the correction of the typographical error and the non-substantive change in the proposed amendment to § 703.21(b)(2)(C). The remaining amendments to Chapter 703 will be adopted as published in the December 4, and December 25, 2015, editions of the *Texas Register* and will not be republished.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on February 19, 2016.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN P. DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	LEGISLATIVE UPDATE – CHANGES TO THE TEXAS PUBLIC INFORMATION ACT, OPEN MEETINGS ACT, AND AGENCY CONTRACTING ACTIVITIES
DATE:	JANUARY 28, 2016

Summary

Texas Administrative Code § 702.21 requires Oversight Committee members to receive training on the Public Information Act (PIA) and the Texas Open Meetings Act (TOMA) after each regular session of the legislature. A comprehensive overview of the TOMA (attached) was provided to Oversight Committee members in August 2014. This memo summarizes changes made to the PIA and TOMA during the 84th Legislative Session. A review of both memos is intended to serve as the required training. This memo also gives an overview of new state laws related to contracting and procurement activities by state agencies. CPRIT legal staff and Oversight Committee members may meet in closed session at the February 17, 2016, meeting for advice and counsel on these issues.

Texas Public Information Act (PIA)

Major amendments to the PIA were adopted by the 2015 legislative session; however, these changes are specific to certain governmental bodies and will not affect CPRIT operations. For example, the PIA was amended to clarify that police departments associated with private universities are subject to the PIA. Another significant change is the adoption of new policies related to body-worn cameras worn by law enforcement officers, such as procedures for requesting and releasing information created by a body-worn camera.

Although no statutory changes impact the PIA's application to CPRIT, some recent court decisions interpreting the Act are relevant to the agency.

- The Supreme Court **expanded the protection of third party information** in *Boeing Co. v. Paxton*, 466 S.W.3d 831 (Tex. 2015), finding that third parties may raise an exception to the public disclosure of their information held by the governmental body if the disclosure would give an advantage to a competitor or bidder. The exception was previously interpreted to be available only to protect the governmental body. Expanding

the exception's application makes it easier for third parties to protect information submitted to state agencies.

Relevance to CPRIT: CPRIT receives a substantial amount of potentially sensitive information from third parties via the grant application and grant monitoring processes. CPRIT has received more than a hundred PIA requests for third-party information. It is in CPRIT's interest to receive third-party information in order to fully evaluate the grant application or grantee progress. However, CPRIT cannot guarantee that the agency will not be ordered by the Attorney General to turn over sensitive information in response to a PIA request. The Boeing decision creates another avenue for third parties to protect their information from public disclosure.

- The Court of Appeals held in *Adkisson v. Paxton,* 459 S.W. 3d 761 (Tex. App.—Austin 2015) that any **government records in the state officer's personal email account related to the state officer's official capacity belong to the governmental body**, not to the state officer in his individual capacity. Correspondence transacting public business is public information subject to disclosure under the PIA even if it occurs via the government official's private email account.

  Relevance to CPRIT: The court's interpretation reiterates the general understanding that correspondence related to official business is subject to the PIA even if the correspondence is in the government official's personal email account.

Texas Open Meetings Act (TOMA)

No changes were made to TOMA in the 84th Legislative Session; however, it is worth reviewing two major changes to TOMA that were made in 2013. First, the 83rd Legislative Session adopted changes to TOMA to allow governing board members to **participate in open meetings via videoconferencing**. However, as noted in CPRIT's 2014 Open Meeting Guidance memo, there are statutory inconsistencies regarding the requirements to be followed. These inconsistencies were not resolved during the most recent legislative session. There are no Attorney General opinions or judicial guidance resolving the inconsistent requirements.

The second major change to TOMA adopted in 2013 allows a **governmental body to use an online message board to communicate outside of open meetings without violating TOMA**. The new law recognizes the power of technology to aid effective functioning of governmental bodies without sacrificing transparency. The electronic message board, which must be viewable by the public, establishes a forum for governing board members to discuss agency business in between traditional meetings. Prior to the change, TOMA restricted officers of the governmental body from communicating as a body about assigned business outside of an open meeting.

There are many statutory requirements to be followed when a government body maintains a message board. The message board must be prominently displayed on the agency's webpage and

may only be used by board members and staff that have received specific authorization. If a posting is taken down, a physical copy of the post must be kept for a minimum of six years. A governmental body may not vote or take an action on an item via the message board.

The first governmental body to put the electronic message board to use is the City of Austin. You can see the city's bulletin board here (click on "View Active Topics" on the message board landing page to see discussion topics.) The City of Austin implemented the message board in the wake of a 21-month criminal investigation into allegations that city council members violated TOMA.

Contracting and Procurement Activities

A major issue addressed during the 84th Legislative Session involved contracting and procurement practices used by state agencies. Most of the changes adopted by the 84th Texas Legislative Session are included in House Bill 1295 (HB1295) and/or Senate Bill 20 (SB20). The legislation enacted requirements and prohibitions affecting governing board members. Below is a summary of these provisions, as well as major provisions addressing enhanced disclosure and reporting requirements.

NOTE: Some state law changes made by SB20 involve agencies' internal controls and processes for evaluating and reporting vendor performance and will not be detailed here. Similarly, the process for purchasing information technology services through the Department of Information Resources substantially changed, but the details are not given here because the impact on board member activities is negligible.

Prohibited Financial Interests

A major change introduced by SB20 bars an agency from entering into a contract if an employee involved in the procurement process or a member of the governing board has a financial interest in the contract. The determination of a prohibited financial interest also includes a family member related within the second degree by affinity or consanguinity to the employee or board member. A financial interest exists if the individual "owns or controls, directly or indirectly, an ownership interest of at least one percent in the person, including the right to share in profits, proceeds, or capital gains; or could reasonably foresee that a contract with the person could result in a financial benefit to the employee or official."

CPRIT Implementation Status: Pursuant to Governor Abbott's direction in early 2015 and prior to the adoption of SB20, CPRIT implemented a process documenting the disclosure of any prohibited financial interest prior to contract execution. As part of this process, the Chief Executive Officer, Chief Operations Officer, General Counsel, and Purchaser complete forms disclosing any financial interest in the proposed contract. Additionally, emails are sent to Oversight Committee members informing board about the potential contract and seeking information on prohibited financial interests. To the extent that a financial interest is noted by an

Oversight Committee member or CPRIT employee, CPRIT cannot contract with the vendor. The completed disclosure forms and emails are saved to the contract file.

Disclosure of Interested Parties

As of January 1, 2016, Texas Government Code § 2252.908 prohibits state agencies from entering into a contract with a business entity unless it has submitted a disclosure of interested parties for certain contracts. This requirement, adopted pursuant to HB 1295, applies to any contract that must be approved by the agency's governing body or has a value of at least $1 million. CPRIT bylaws requires all contracts of $100,000 or more to be approved by a vote of the Oversight Committee.

A business entity wishing to execute a contract with CPRIT is required to submit a list of interested parties and the signature of the authorized agent acknowledging that the disclosure is made under oath and penalty of perjury. CPRIT must then submit a copy of the disclosure to the Texas Ethics Commission (TEC). The required forms and administrative rules implementing the new statutory requirement are available on the TEC's website.

CPRIT Implementation Status: CPRIT has not entered a contract valued at $100,000 since the January 1, 2016, implementation date; the agency is prepared to implement the new vendor disclosure requirements.

Posting Requirements

Changes to state law also introduced new posting and publishing requirements that CPRIT must follow. Texas Government Code § 2261.253(a) requires each state agency to post on its website every request for proposal and contract for the purchase of goods or services. If a contract is not competitively bid, the agency must post the statutory authority it relies upon justifying an exception to the competitive bidding process. In addition, each state agency must post on its website contracts that require enhanced contract monitoring and the established clear levels of purchasing accountability and staff responsibilities related to purchasing. Agencies are also required to publish a contract management handbook with policies and practices to be followed that are consistent with the comptroller's contract management guide.

CPRIT Implementation Status: CPRIT is working to post all contracts entered into on or after September 1, 2015, on its website as required by the new law. CPRIT has posted a draft of its Procurement Plan and Contract Management Handbook on its website under the procurement section.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN PAULING DOYLE, GENERAL COUNSEL
SUBJECT: OPEN MEETINGS GUIDANCE
DATE: AUGUST 13, 2014

Summary

Texas Government Code Chapter 551, commonly referred to as the Open Meetings Act (the Act), mandates that meetings of governmental bodies such as the Oversight Committee be open to the public, except for specific situations. This memorandum addresses scenarios when the Act applies to communications between Oversight Committee members.

Determining whether the Act applies to a discussion of Oversight Committee members is important because a meeting subject to the Act must comply with specific requirements. These requirements include providing public notice of the meeting at least seven days prior to the day of the meeting, posting an agenda of items to be discussed, and holding the meeting so that the public may see and hear the discussion and action(s) taken by the governing body.

This is intended to be an overview of issues related to communication between Oversight Committee members. If you have specific questions or need more information, please contact me directly at 512/305-8486.

Background – Texas Open Meetings Act

For nearly five decades, state law has mandated that, "Every regular, special, or called meeting of a governmental body shall be open to the public, except as provided by [Chapter 551 of the Texas Government Code]."[1] The purpose of the Open Meetings Act, as interpreted by the Texas Supreme Court, is "to safeguard the public's interest in knowing the workings of its governmental bodies."[2] That interest is not served solely by informing the public of the outcome of a governing body's decision on a particular issue.

[1] Tex. Gov't. Code Ann. § 551.002
[2] *Cox Enter., Inc. v. Bd. of Trs. of Austin. Indep. Sch. Dist.*, 706 S.W.2d 956, 960 (Tex. 1986).

Instead, public interest is satisfied only when the public is able "to observe how and why every decision is reached."[3]

By law, deliberations and discussions of a governing board for a state entity like CPRIT must be conducted in public pursuant to an agenda posted publicly for seven days before the day of the meeting. The governing body's discussion and action is limited to the items listed on the published agenda. The meeting location must be open and accessible to the public.

State law requires elected and appointed public officials to receive at least two hours of Open Government training within 90 days of the member's appointment; one hour must be dedicated to Open Meetings and one hour must be related to the Public Information Act.[4] According to the Attorney General, "The law imposes no specific penalty on officials who fail to attend open government training. The purpose of the law is not to punish public officials, but to foster open government by making open government education a recognized obligation of public service."[5]

The Office of the Attorney General (OAG) reports that most cases involving open government violations result from public officials simply not knowing what the law requires. The OAG provides the free video training courses as well as publishing several guides to assist governmental bodies in understanding their obligations under the Act.

When Does the Act Apply To Communications Between Members?

Generally, the Act's requirements (e.g. public notice, posted agenda, meeting open to the public) apply whenever a quorum of the governmental body meets to deliberate the governmental body's public business.

- What is a quorum? For most governmental bodies, including the Oversight Committee, the presence of a simple majority of the appointed members makes up a quorum. A quorum is required in order to convene a meeting. There have been no decisions about whether the meeting must immediately adjourn when a quorum is lost, however, the governmental body cannot take final action without a quorum.

  Although a quorum is generally thought of in terms of *physical* presence, the Attorney General and Texas courts have determined that a quorum may exist even if the members are not physically present in the same location. For example, circulating a group letter among the governmental body members for signatures may constitute a "meeting" subject to the Act even though the members were not physically together.[6] Similarly, a "meeting" subject to the Act may occur if a quorum of members participates in a conference call or group email.

[3] *Acker v. Tex. Water Comm'n*, 790 S.W.2d 299, 300 (Tex. 1990).
[4] Tex. Govt. Code §§ 551.005 and 552.012.
[5] https://www.texasattorneygeneral.gov/open/og_training.shtml#3, "Frequently Asked Questions about Open Government Training."
[6] Tex. Att'y Gen. Op. No. DM-95 (1992).

Meetings by conference call or group email are not permitted by the Act, but usually occur inadvertently. However, a criminal offense occurs if "a member or group of members of a governmental body…knowingly conspire to circumvent [the Act] by meeting in numbers less than a quorum for the purpose of secret deliberations in violation of [the Act]." Tex. Govt. Code Ann. § 551.143. See the section, "What is a Walking Quorum?" for more guidance on this subject.

- What is considered a meeting? An opportunity to deliberate about the governmental body's public business is regarded as a meeting. Courts have construed "deliberation" broadly when interpreting the Act. An action or vote is not required for deliberation to have occurred. Listening to information conveyed by another person may be enough to invoke the Act, even if no action is taken and there is no discussion by the members.[7] For this reason, staff briefings and work sessions are considered "meetings" under the Act if a quorum attends, whether or not discussion or final action takes place.

Are There Any Situations When the Act Does Not Apply?

Yes. The Act does not apply to certain situations even though a quorum of the governmental body is present. No action related to public business may be taken by the governmental body in order for the exception to apply in these specific circumstances. Exceptions to the Act recognized by state law are:

- social functions unrelated to the board's public business;
- conventions or workshops;
- ceremonial events;
- press conferences; and
- public testimony or comments at legislative agency meetings or legislative committee meetings.

Because the Act does not apply, requirements such as notifying the public, posting an agenda, and opening the meeting room to the public, are not mandated.

What About Closed Sessions?

The Act recognizes certain exceptions to public discussion for specific topics. Under the Act, the Oversight Committee may hold a closed meeting (also referred to as an "executive session") for one or more of the following eight reasons:

1. Consideration of specific personnel matters;
2. Consultations with its attorney;
3. Discussions about the value or transfer of real property;
4. Discussions about security personnel, security devices, or a security audit;

[7] S*ee Bexar Medina Atascosa Water Dist. v. Bexar Medina Atascosa Landowners' Ass'n*, 2 S.W.3d 459, 462 (Tex. App.--San Antonio 1999, pet. denied) (deliberations took place at informational gathering of water district board with landowners in board member's barn, where one board member asked questions and another board member answered questions, even though board members did not discuss business among themselves).

5. Discussions about a prospective gift or donation to a governmental body;
6. Discussions of certain economic development matters;
7. Certain information relating to the subject of emergencies and disasters; and
8. Discussion of an ongoing compliance investigation related to fraud, waste, or abuse of state resources.

Although the requirement that board deliberations take place in public does not pertain for these eight topics, the Act still applies. The items to be discussed in closed session must be appropriately noticed and the meeting convened first in open session. Closed sessions are only for deliberations. Any vote or final action related to a matter discussed in closed session must take place in an open meeting.

Does the Act Apply to Oversight Committee Subcommittee Meetings?

No. Meetings of Oversight Committee subcommittees need not comply with the requirements of the Act because a quorum of members is not present and the subcommittees are not authorized to take final action on behalf of the Oversight Committee.

In most cases, a meeting of a quorum of members is necessary in order for the Act to apply. However, the Act will apply to a subgroup of governmental body members *if the subgroup has the authority to make final decisions on behalf of the governmental body*. This is the case even if the subgroup's membership is less than a quorum of the governmental body's members. For example, a meeting of governmental body's executive committee must comply with the Act's requirements whether or not a quorum of the full board attends if the executive committee has been delegated the authority to bind the larger body.

No subcommittee currently constituted under the Oversight Committee Bylaws is authorized to take final action on behalf of the Oversight Committee; subcommittee activity is limited to recommending an action to be taken by the Oversight Committee. Those recommendations are discussed in the open meeting before an action is taken by the Oversight Committee and are not simply rubberstamped.

On a related matter, the Act does not apply to a group of Oversight Committee members that meets with a public or private group so long as there is not a quorum of Oversight Committee members. For example, the Act does not apply to a meeting of three Oversight Committee members and the University Advisory Committee.

Is a Conference Call or an Email Between Members Considered a "Meeting"?

[*This section addresses discussions between Oversight Committee members that occur by telephone or by email. Guidance regarding participation in an open meeting via telephone or videoconference is a different issue that is addressed in the section, "Can an Oversight Committee Member Participate in Open Meeting by Phone or Video Conference?" Guidance related to a new statutory provision that permits electronic*

communication among board members via an online message board is addressed in the section, "Are There Other Ways for a Quorum of the Oversight Committee to Communicate Electronically?"]

A conversation about public business taking place among two to four Oversight Committee members does not in itself constitute a violation of the Act. In most cases, there must be a quorum of members present when a discussion of public business occurs in order for requirements of the Act to apply. This is the case even if the conversation is conducted over the telephone or by electronic mail. Subcommittee business may be conducted by telephone or email because a quorum of Oversight Committee members is not present.

However, members of a governmental body should be wary because technology such as conference calls and electronic mail make it easier to hold serial discussions among members about public business in private. Using telephone conversations or electronic communication (including texting) with the intention to conduct deliberations about public business in private may result in criminal violations even if a quorum is not part of the call or email.[8] See the discussion about "walking quorums" for more guidance.

Even if it is not intentional, discussing public business by phone or email with a quorum of members may be a violation of the Act. This can occur when one board member sends an email about public business to four or more board members, or forwards an email discussion about public business between some board members to other board members. Whether certain phone conversations or emails between members constitute a violation of the Act is a fact issue.[9]

What is a Walking Quorum?

A walking quorum occurs when (1) a series of smaller group meetings (less than a quorum) occur; and (2) the smaller group meetings are intentionally set up to avoid constituting a quorum and evade the requirements of the Act.[10] Walking quorums are not limited to physical meetings. It may be a violation of the Act if the members meet or communicate by phone, memo, text, or email in numbers less than a quorum with the specific intent to hold secret deliberations and circumvent the Act.

Can an Oversight Committee Member Participate in an Open (or Closed) Meeting by Phone or Video Conference?

Yes, under limited circumstances. Participation by phone may occur in the event of an emergency when convening a quorum is difficult of impossible. The Act permits holding an open or closed meeting by video conference, but legislation adopted in 2013 related to video conferences includes conflicting requirements regarding the location of video conference and the notice required under the Act.

[8] Tex. Gov't Code Ann. § 551.143.
[9] *See Hitt v. Mabry*, 687 S.W.2d 791 (Tex. App. B San Antonio 1985, no writ) (school trustees violated Act by telephone conferencing). *But see Harris County Emergency Serv, Dist. #1 v. Harris County Emergency Corps*, 999 S.W.2d 163 (Tex. App. B Houston [14th Dist.] 1999, no writ) (evidence that one board member of a five member county emergency service district occasionally used telephone to discuss agenda for future meetings with one other board member did not amount to Act violation).
[10] Tex. Govt. Code Ann. § 551.143.

- Participating in a Meeting by Phone - Governing bodies may not conduct meetings subject to the Act by phone unless the following two requirements are met: an emergency or public necessity exists and convening a quorum in one location is difficult or impossible.[11] An emergency or public necessity exists only in the event that the governmental body is required to take immediate action resulting from: (1) an imminent threat to public health or safety or (2) a reasonably unforeseeable situation. Whether an emergency exists is a fact-based question subject to judicial review. However, a member may not participate by phone even in an emergency scenario if a quorum of the Oversight Committee meets in one location because one of the requirements of participation by telephone is that convening a quorum in one location is difficult or impossible.

  If both requirements are met and one or more members participate by phone, then the meeting must be audible to the public at the location specified in the notice with two-way communication available during the entire meeting. The meeting must be recorded with every party identified before speaking.

- Participating by Video Conference – A governing body may hold an open or closed meeting by video conference when a quorum of the members is present in one location with a live video and audio feed of the member participating remotely.[12] The member presiding over the meeting must be physically present at the location open to the public.

  Although this may appear relatively straightforward, two bills adopted by the 83rd Texas Legislature, HB 2414 and SB 984, have conflicting provisions regarding key requirements of the sections applicable to video conference meetings. One contradictory provision is whether the governing body must make available to the public "at least one physical space located in or within a reasonable distance of the geographic jurisdiction, if any, of the governmental body that is equipped with videoconference equipment that provides an audio and video display, as well as a camera and microphone by which a member of the public can provide testimony or otherwise actively participate in the meeting." Complicating this further, another conflict in the statute compels different outcomes in the event that the video conference feed is not visible and/or audible to the public.

  OAG guidance states, "The enactment of House Bill 2414 and Senate Bill 984 raises many questions, none of which have been addressed by a judicial opinion. Until such time as the Legislature addresses these questions, any governmental body seeking to hold a meeting by a videoconference call should first consult its legal counsel."[13]

[11] Tex. Govt. Code Ann. §§ 551.121 - .126.
[12] Tex. Govt. Code Ann. 551.127
[13] *2014 Open Meetings Handbook*, p. 22, Office of the Attorney General, https://www.texasattorneygeneral.gov/AG_Publications/pdfs/openmeeting_hb.pdf

While provisions related to an Oversight Committee member's participation by video conference are not clear, the law unequivocally allows the Oversight Committee to permit a member of the public to testify at a meeting from a remote location by video conference.

Are There Other Ways for the Entire Oversight Committee to Communicate Electronically?

Yes. The 83rd Legislative Session amended the Act to permit communications about public business between members of a governmental body and its staff to take place electronically so long as the communication is written and posted to an online message board that is accessible to the public. Such a discussion "does not constitute a meeting or deliberation," under the Act. However, the governmental body may not vote or take any action via posting to the online message board.

The online message board must be owned or controlled by the governmental body and be publicly accessible within one click from the governmental body's home page. The communication must be displayed in real time, attributable by the name and title of the member or staff, and viewable for at least 30 days after the communication is first posted (and retained for six years).

What are the Consequences for Violating the Act?

Actions taken in violation of the Act are voidable. Certain violations of the Act can also result in criminal penalties for board members if the intent to avoid or violate the Act's requirements is proven. Criminal violations include knowing participation in a walking quorum or in an unauthorized closed meeting.